UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARIUSZ MAZUREK, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, vs. SERES THERAPEUTICS, INC., ROGER J. POMERANTZ, and MICHELLE TRUCKSIS, Defendants.	Case No. 2:15-cv-01522-NBF **CLASS ACTION** **AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **Jury Trial Demanded**

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Lead Plaintiffs Erste-Sparinvest Kapitalanlagegesellschaft mbH ("Erste-Sparinvest") and Oklahoma Law Enforcement Retirement System ("OLERS"), individually and on behalf of a class of similarly situated persons and entities allege the following against Seres Therapeutics, Inc. ("Seres" or the "Company") and the Individual Defendants, upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters. Lead Plaintiffs bring this federal securities class action on behalf of themselves and a class consisting of all persons and entities who purchased the common stock of Seres from June 25, 2015, through and including July 29, 2016 (the "Class Period"), and were damaged thereby. The Defendants in this action are Seres; Roger Pomerantz ("Pomerantz"), the Company's President, Chief Executive Officer ("CEO") and Chairman of the Board of Directors; and Michele Trucksis, the Company's Chief Medical Officer ("CMO") and Executive Vice President. Lead Plaintiffs and the Class's claims arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule l0b-5 promulgated thereunder.

I. INTRODUCTION

1. On July 29, 2016, Seres announced that the Phase 2 clinical trial for its most promising drug candidate – SER-109 – had failed miserably. Not surprisingly, this news sent Seres's stock tumbling. On Thursday, July 28, 2016, Seres stock price had closed at $35.77, and by Monday, August 1, 2016, it closed at $9.73, losing 72% of its value. The July 29 news of SER-109's failure may have surprised public shareholders. It did not, however, surprise Defendants.

2. In the weeks leading up to the announcement of Phase 2's failure, Defendants were busy selling shares – *a lot of shares*. Between July 2, 2016, and July 29, 2016, Defendants Pomerantz and Trucksis, and insider John Aunins (Seres's Chief Technology Officer) collectively sold Seres stock for proceeds of ***$5,425,951***. Of these sales, ***$2,507,527*** happened on July 27 and July 28 – just two days before Seres announced that Phase 2 failed.

3. Taken alone, these stocks sales are highly suspicious. But there is much more to this case than just insider trading. By February 2016, Defendants did not expect Phase 2 to succeed because they had learned that it was failing. And, even before that, Defendants had made promises about Phase 2's potential for success that were simply not true. In sum, on July 29, the public took a bath. Defendants did not join in those losses. This Complaint tells the story of how that happened.

4. Seres is a start-up pharmaceutical company that develops biologic drugs to treat the human microbiome – the bacteria, fungi, and viruses that live in a person's gut. Seres's lead biologic candidate is SER-109, a proposed treatment for recurrent *clostridium difficile* infection, or "CDI." CDI is a serious intestinal disease that results from an imbalance – or "dysbiosis" – of the intestinal microbiome. There are approximately 700,000 CDI cases reported per year in the U.S., and 29,000 deaths. There is currently no effective pharmaceutical treatment for recurrent CDI.

5. In 2014, Seres completed Phase 1b/2 of its first SER-109 clinical trial. Though small, the trial was highly successful. Of the 30 patients enrolled, the Company reported that 29 were cured of recurrent CDI. Armed with this impressive data, Seres and its executives rushed to initiate Phase 3 trials of SER-109 and complete its initial public offering ("IPO"). The IPO went forward as intended. On the strength of its Phase 1b/2 data and the promise of SER-109, Seres raised $134 million from public investors, and on June 26, 2015, its first day of public trading, Seres's shares closed at a promising $51.40.

6. Unlike its IPO, Seres's Phase 3 trials did not go as planned. In fact, they did not go at all. The Food and Drug Administration ("FDA") raised two chief concerns about Seres proceeding directly to Phase 3: Seres's manufacturing capability and the SER-109 capsule. In

Phase 1b/2 trials, Seres did not manufacture SER-109 at all but instead outsourced manufacturing to four individual clinical testing sites. And, in Phase 1b/2, SER-109 required up to 15 doses a day for two days – which would be difficult to market. Thus, Seres needed to show the FDA that it could manufacture SER-109 in a commercially viable manner, i.e., produce a drug that can be taken using a consumer-friendly dosage schedule.

7. The FDA's intervention led to several critical changes. First, Seres began manufacturing SER-109 in-house for the first time. Second, Seres changed the formula for the SER-109 capsule. This "new formulation" required only four doses per day and the encapsulation was modified. Based on these substantial changes to SER-109, the FDA required Seres to conduct a Phase 2 study of the "new formulation" of SER-109 before moving to Phase 3. *See* June 5, 2015 Letter from the SEC to R. Pomerantz attached as Ex. A ("Please also confirm that FDA has specifically requested that you evaluate your new formulation of SER-109 prior to commencement of Phase 3 studies.").

8. Phase 2, also called "ECOSPOR," tested the "new formulation" of SER-109 and began in May of 2015, with the first patient dosed on May 28th. Phase 2 included 89 patients, enrolled on a rolling basis. Patients were dosed with SER-109 or a placebo at a 2:1 ratio. The Phase 2 endpoint was 8 weeks without a recurrence of CDI, and its anticipated endpoint was March 2016. Unlike the patients in Phase 1b/2, however, Phase 2 enrollees were receiving the "new formulation" of SER-109 created in Seres's new in-house manufacturing facilities. The "new formulation" had never been tested for efficacy in humans. It was a different pill, manufactured in a different place, by different people, using different manufacturing processes.

9. The U.S. Securities and Exchange Commission ("SEC") took notice of these changes. In spring of 2015, the SEC wrote to Seres and asked it to explain in its Form S-1

Registration Statement the changes to the Phase 2 study and to SER-109's formulation. *See* Ex. A. The SEC recognized that "investors are entitled to disclosure reflecting concerns expressed by the FDA where such concerns resulted in a material change to your clinical development program for your most advanced product candidate . . . ." *Id.* In response, Seres included language in its S-1, claiming that the Phase 2 version of SER-109 was "***more pure***" and "***comparable in potency***" to the pill used in Phase 1b/2. *See* June 22, 2015 Letter from Peter Handrinos to SEC, attached as Ex. B.

10. And so, Defendants spread a series of lies that led shareholders to lose millions while insiders, who were privy to the disappointing results, sold out to avoid those same losses. During the Class Period, while Phase 2 was ongoing, Defendants made three categories of statements that were either materially false, misleading, or both.

11. First, Defendants failed to tell shareholders what they likely knew ***as early as February 2016*** – that Phase 2 would not produce the same strong results as Phase 1b/2. This is particularly true as to Defendant Trucksis, whose primary responsibility was to be the liaison between the Company and the clinical sites and to receive incoming trial data. By early February 2016, Seres had either completed its target enrollment of 87 patients or was very close to it. Indeed, on February 5, 2016, the Company was still reporting March 2016 as the "anticipated" date that the eight week data would be complete. Even more, the FDA required the clinical sites to report any serious adverse events (SAEs) to the trial sponsor (here, Seres) immediately. Seres would then have to discern the probable cause of the SAE and report that promptly to the FDA. Seres ultimately reported in January 2017 that there were many SAEs during Phase 2.

12. After patients had failed the blinded trial, they were given the opportunity to receive a dosage of SER-109 as part of an open label study, where the patients knew that they were

receiving the drug and not the placebo. By early 2016, Defendants had access to the enrollment data for most of the patients in the open-label extension arm of Phase 2 and had access to the 8-week endpoint failure data for most of the patients in Phase 2. This data showed Defendants that (a) more people were failing than expected and (b), as a matter of pure statistics, the number of patients failing the SER-109 arm was larger than expected. Tellingly, Defendant Pomerantz entered into a stock trading plan on the same day as Defendant Trucksis on February 26, 2016, and like Trucksis, sold millions of dollars of Seres shares before the disappointing results were eventually made public.

13. Given this information, Defendants either knew or recklessly disregarded that Phase 2 was not going to produce the same successful results seen in Phase 1b/2. Yet, Defendants said nothing between February 2016 and July 2016 to caution their shareholders. Quite the contrary, they continued to lead shareholders to believe that Phase 2 would reproduce Phase 1b/2's results. And it worked. As late as July 12, 2016, Seres held a "Management Dinner" for analysts. After the dinner, Cowan and Company and Leerlink both published very positive reports, and between July 11 and 18, 2016, Seres's stock price increased 10.7%.

14. Second, throughout the Class Period, Defendants told shareholders that the SER-109 capsule in Phase 2 was just as ***potent*** as the SER-109 tested in Phase 1b/2. Defendants had no basis for such a statement. Seres had never tested the "new formulation" of SER-109 in humans. Yet, in August 2015, Pomerantz appeared on "Mad Money" with Jim Cramer to promote SER-109. Pomerantz dramatically removed a pill from a bottle and claimed that it had "one times ten to the eighth bacteria in spore form in there and you take four of them once and ***that's how we cured 97% of people with CDI***, with c. diff. infection."

15. This was both materially false and misleading. The SER-109 pill in Phase 2 was ***not the same pill*** that achieved a 97% cure rate in Phase 1b/2, and most of the SER-109 pills in Phase 1b/2 had a much larger dose of spores than 1×10^8. Seres recently acknowledged "that suboptimal dosing in some patients may have contributed to the previously reported SER-109 Phase 2 study outcome." In other words, despite Defendants' representations, the "new formulation" of SER-109 was not "comparable in potency" to the SER-109 used in Phase 1b/2.

16. Third, Defendants led shareholders to believe that the protocol for Phase 2 was nearly identical to Phase 1b/2, implying that Phase 2 would generate similar results. In September 2015, for example, Pomerantz claimed the trials were "highly similar." According to him, the "main difference" between the two trials was the geographic location of the clinic sites. At a Goldman Sachs Global Healthcare conference in June 2016, Pomerantz claimed the differences between the two trials were "minimal." In February 2016, Defendant Trucksis claimed that Phase 2 "was like the first study" immediately after touting the "amazing" and "remarkable" results in Phase 1b/2.

17. Defendants either knew these statements were materially false or misleading or recklessly ignored that fact. Seres had intended to go directly to Phase 3, but was not able to because the FDA demanded that it validate its manufacturing capabilities and test a "new formulation" – a commercially viable form – of SER-109. These were the significant changes in Phase 2, and the SEC had already notified the Company that it viewed these developments as "***substantial***" and "***material***" modifications. *See* Ex. A.

18. On July 29, 2016, Seres announced that Phase 2 did not achieve its primary endpoint when compared to a placebo. SER-109 failed to be even marginally more effective than placebo, i.e., no treatment at all. And thus, public shareholders paid the price for Defendants' false

and misleading statements. As noted, however, Defendants themselves did not because in the months before announcing the failure of Phase 2, they exercised and sold millions of dollars in Seres stock options. That was securities fraud.

II. JURISDICTION AND VENUE

19. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. § 240.10b-5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

20. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b), because Seres's principal executive office is located within this District at 200 Sidney Street, Cambridge, MA 02139, and many of the acts and practices complained of herein occurred in substantial part in this District. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Lead Plaintiffs

21. On December 28, 2016, this Court appointed Erste-Sparinvest and OLERS to serve as Lead Plaintiffs in this action pursuant to the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). *See* ECF No. 28.

22. Erste-Sparinvest is an investment company based in Vienna, Austria. As part of Erste-Sparinvest's asset management services, it is responsible for managing mutual funds, private funds, and institutional funds. As set forth in its certification, ECF No. 10-1, during the Class

Period, Erste-Sparinvest's funds purchased shares of Seres common stock and suffered damages as a result of the securities law violations alleged herein.

23. OLERS administers retirement and medical benefits for members of the law enforcement profession of the state of Oklahoma and their families. OLERS manages more than $880 million in assets on behalf of members and beneficiaries. As set forth in its certification, ECF No. 22-2, during the Class Period, OLERS purchased shares of Seres common stock and suffered damages as a result of the securities law violations alleged herein.

B. Defendants

1. The Company

24. Defendant Seres is headquartered in Cambridge, Massachusetts. The Company's common stock is listed and trades actively on the NASDAQ stock market, under the ticker symbol "MCRB." As of March 7, 2016, the Company had more than 39 million shares of common stock outstanding.

25. Seres is a pharmaceutical company developing a novel class of biological drugs that treat disease by restoring the function of a dysbiotic microbiome. The human microbiome is an ecology of microorganisms, including bacteria, fungi and viruses. Dysbiosis is when these microorganisms become imbalanced and leave the body more susceptible to infections, metabolic disorders, allergies, autoimmune disease, inflammation and other conditions. Seres's drugs are supposed to repair or rebalance a dysbiotic microbiome.

2. The Individual Defendants

26. Defendant Pomerantz serves as Seres's President, CEO, and Chairman of the Company's Board of Directors. Pomerantz has served as the Chairman of the Board of Directors of Seres since November 2013. Pomerantz has served as served as both CEO and Chairman since

June 2014. Before joining Seres, Pomerantz was Senior Vice President and Worldwide Head of Licensing & Acquisitions at Merck & Co., Inc. ("Merck").

27. Defendant Michele Trucksis has served as Seres's CMO and Executive Vice President since January 2015. Prior to joining Seres, Trucksis served as Executive Director of Merck Research Laboratories with responsibility for clinical and global product development functions and development strategy in antibacterials, antifungals, and anti-cytomegalovirus drug candidates.

28. Defendants Pomerantz and Trucksis are collectively referred to herein as the "Individual Defendants." Defendant Seres and the Individual Defendants are collectively referred to herein as the "Defendants."

IV. FACTUAL BACKGROUND

A. Seres Reports Promising Results From Phase 1b/2 Study of SER-109

29. CDI is a debilitating infection of the colon and a leading cause of hospital-acquired infection in the United States. Each year CDI kills approximately 29,000 Americans. Once a patient contracts CDI, because it is antibiotic resistant, the rate of recurrence is high. After the initial infection with CDI, the risk of recurrence is 25%. After the second infection, the risk of recurrence is 40% and for patients with two or more infections, the rate of recurrence is higher than 60%.

30. Although not always, many times a patient develops CDI following treatment with antibiotics. A healthy adult's intestines are host to a mixture of bacteria, fungi, and viruses that make up the "microbiome." Antibiotic treatment kills "bad" bacteria that cause infection, but in the process it also kills "good" bacteria causing "dysbiosis." Dysbiosis is an unbalanced state within the microbiome. In laymen's terms, this simply means that the bacteria and viruses in a

patient's intestines are unbalanced, meaning they do not have enough "good" bacteria and have too much "bad" bacteria.

31. Currently, the best treatment for recurrent CDI is fecal microbiota transplant or "FMT." FMT, when performed in ideal conditions, has 90% efficacy rate in curing CDI. To perform FMT, physicians take a stool donation from a healthy adult and transplant it into the intestines of a patient suffering from CDI using a nasal tube, a colonoscopy, or a capsule. FMT is not, however, a drug or a pill that can be easily manufactured. And because it involves the transplantation of biologic material from one person to another – like a blood transfusion – it involves the risk of transferring disease from one person to another. For this and other reasons, FMT is not FDA-approved and a patient must specifically elect to undergo the procedure.

32. As a result of these unique risks, there is a great need for a commercially available pill that will accomplish the same results as FMT with lower risks. A number of companies have been exploring ways to achieve the effects of FMT through a more traditional pharmaceutical, i.e., a pill or pills. SER-109 is Seres's lead product candidate and is designed to fill this niche. In theory, SER-109 cures CDI by restoring the microbiome to a healthy, balanced state that existed before infection and before treatment with antibiotics. Using computer technology, Seres identified the bacterial spores that characterized a healthy adult's microbiome. After isolating the spores from a healthy stool donor, Seres eliminates pathogens and then encapsulates the spores.

33. In 2013 and 2014, Seres conducted a Phase 1b/2 clinical study of SER-109. Phase 1b/2 was modest and investigational. It involved only 30 patients and was designed to analyze the safety and efficacy of SER-109 in humans. Four clinical sites participated in the study – Massachusetts General Hospital (Boston, Massachusetts); Emory University Hospital (Atlanta,

Georgia); the Mayo Clinic (Rochester, Minnesota); and Miriam Hospital (Providence, Rhode Island).

34. Seres's June 16, 2015 Form S-1 Registration Statement (the "S-1") described Phase 1b/2 as follows:

> The Phase 1b/2 clinical study was a two part trial designed to evaluate the safety and efficacy of SER-109 in approximately 30 patients with recurrent CDI, defined as three or more occurrences of CDI in the previous 12 months.
>
> Part 1 of the study evaluated a single dose of SER-109 administered orally in 30 capsules over two days, with the dose derived from approximately 75 grams of stool. Part 2 of the study evaluated a single dose of SER-109 administered orally in a range of one to 12 capsules over one day. The dose in Part 2 was based on spore count, as opposed to fecal mass, which is expected to allow for a more precise dosing regimen. The target dose in Part 2 was $1x10^8$ spores per dose, which was approximately 17-fold lower than the mean dose in Part 1. The SER-109 doses were derived from seven different healthy human donors. . . .
>
> The trial was designed to enroll patients between the ages of 18 and 90 years, with relapsed, laboratory-confirmed CDI with three or more occurrences in the previous 12 months. Enrolled patients must have undergone treatment for CDI with at least three courses of antibiotic therapy in the last 12 months and have a life expectancy of greater than three months. . . .
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> [T]he primary efficacy measure was the absence of CDI (defined in this study as more than three unformed bowel movements in a 24-hour period with laboratory confirmation of the presence of C. difficile toxin in the stool) during the eight weeks after initiating therapy. Eight weeks was selected as the measurement period for the primary endpoint based on our clinical advisory board's experience that a significant majority of CDI recurrences occur within eight weeks. . . .

35. The results of Phase 1b/2 were very promising. On September 8, 2014, Seres announced final data from Phase 1b/2 in a press release. According to Seres's S-1, SER-109 showed a "clinical cure rate" of "97%":

> *Efficacy*. Twenty-six of 30 patients, or 87% of patients, in the Phase 1b/2 clinical study achieved the primary efficacy endpoint of experiencing no recurrence of CDI during the eight weeks post-treatment. These 26 patients consisted of 13 patients in each of Part 1 and Part 2 of the study. Among the 26 patients was one patient who experienced an initial recurrence on Day 26 and was re-treated, per protocol,

> with a dose from the same donor. Following re-treatment, this patient also achieved the primary efficacy endpoint. Efficacy results were not dependent upon the initial human donor or the dose over the range of $3.4x10^7$ to $2.3x10^{10}$ spores.
>
> Of those patients who did not meet the primary efficacy endpoint, one patient had a recurrence of CDI on Day 5 and did not receive a second treatment with SER-109. The three other patients who failed the protocol-defined primary efficacy endpoint were determined by their attending investigator to be recovering from their diarrheal episode by the time they submitted their stool sample for CDI testing. In each case, the investigator advised the patient to refrain from antibiotic use and the patients' condition resolved without antibiotic therapy. All three patients were determined to be clinically CDI free at eight weeks. As a result, the clinical cure rate for the study, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing, was 97%, or 29 of 30 patients.

36. Despite the promising results, Phase 1b/2 had many limitations. In addition to only testing a small number of patients, Seres conducted the study without submitting an investigational new drug application ("IND") to the FDA. According to Seres's S-1, the "FDA provided confirmation that it intends to exercise enforcement discretion with respect to our Phase 1b/2 clinical study of SER-109, a modified FMT product, and accordingly, we did not conduct this trial under an IND." This simply means that the FDA could have required an IND, but it did not.

37. The lack of an IND is important. The FDA typically requires an IND before a sponsor company may clinically test a drug. An IND ensures that the FDA has reviewed the testing and manufacturing protocols the company plans to use. It also insures that investors and the public have basic data about the tests performed on the drug. In particular, in this case, an IND would have required Seres to get the FDA's feedback and approval on its Chemistry, Manufacturing, and Controls ("CMC") protocols for SER-109, as well as the criteria the Company used to admit patients into Phase 1b/2. Because, however, Seres did not operate under an IND, this oversight was lacking, as was the detailed disclosure that accompanies a clinical trial conducted under an IND.

38. Lead Plaintiffs consulted with a regulatory expert, Nancy Chew, as part of their investigation into the events surrounding this Complaint. Ms. Chew has guided six orphan drugs through the FDA approval process. She is the Senior Advisor for New Product Development and Submissions at EAS Consulting Group, LLC. She has been guiding drug and device companies through the regulatory process for over forty years and has published journal articles, book chapters, and various magazine articles and columns on the process. Her resume is attached as Ex. C to this Complaint.

39. Ms. Chew confirmed that when a company submits an IND application, it must submit information to the FDA regarding its manufacturing processes. Regulation 21 C.F.R. §312.23(a)(7)(i) states that for those investigations covered by the IND, "sufficient CMC information [must be provided] to assure the proper identification, quality, purity and strength of the investigational drug."

40. Ms. Chew further confirmed that an IND application (21 C.F.R. Part 312.23) must contain information regarding CMC, and the absence of an IND in Seres's Phase 1b/2 study allowed Seres to conduct the study with absolutely no FDA oversight of the method of preparation of the FMT test article that was administered to patients. The FDA's requirement that Seres establish its own manufacturing site for its Phase 2 study meant that Seres had to build, rent, or buy a manufacturing suite that met Good Manufacturing Practices standards and submit CMC, pharmacology/toxicology, and clinical information in the IND document. For the CMC portion of the IND, Seres had to submit sufficient CMC information to assure proper identification, quality, purity, and strength of its investigational FMT material. The amount of detail of CMC information increases through the phases of the clinical program, but the CMC component of the IND must address:

Drug Substance

- Description
- Characterization
- Manufacturer
- Method of Manufacture

Drug Product

- Composition
- Manufacture
- Drug Product Specification
- Stability
- Environmental Assessment

41. Ms. Chew states that moving the manufacturing operation from a third party to a new facility generally requires 18 to 24 months. Seres announced the final data from Phase 1b/2 in September of 2014, met with the FDA, and dosed the first Phase 2 patient in May of 2015 – a period of about eight months. Ms. Chew believes that it is highly likely that flawed development of CMC methods and data is at least partly responsible for the failure of the Phase 2 study.

42. As Ms. Chew points out, the absence of the IND in Phase 1b/2 allowed Seres to not disclose the details of its manufacturing processes to the FDA.

B. The FDA Requires Seres to Test the "New Formulation" of SER-109 Before Moving to Phase 3 Clinical Trials and the SEC Takes Note of the Significant Changes Made to Seres' Lead Product Candidate

43. With the success of Phase 1b/2 under their belts, Defendants rushed to conduct a Phase 3 trial, the quickest route to marketing and selling SER-109 commercially. The FDA, however, had other plans. Although exercising its discretionary enforcement authority and accepting the results of the Phase 1b/2 study without an IND, the FDA now required Seres to conduct its next trial of SER-109 under an IND and required Seres to test "SER-109 product that is manufactured in a manner identical to the product that will be manufactured post-licensure."[1]

[1] *See* Seres Health, Inc., Amendment No. 1 to Registration Statement (Form S-1), at 10 (June 16, 2015).

That is, the FDA wanted Seres to test the SER-109 that it was actually going to sell, to prove that it could manufacture the drug in a commercially viable manner and validate the manufacturing processes the Company planned to use. This led to significant changes between Phase 1b/2 and the Phase 2 trial, and ultimately the downfall of the Phase 2 study.

44. First, Seres began manufacturing SER-109 itself in-house for the *first time*. This represented a substantial change from Phase 1b/2. SER-109 is composed of bacterial spores called Firmicutes that live in the gut of a healthy adult, which are derived from healthy donor stool samples. Scientists take the stool, isolate the appropriate Firmicutes spores in the donation, eliminate any harmful pathogens from the stool, and ultimately put the material into a capsule.

45. In Phase 1b/2, however, Seres did not manufacture SER-109 at all. Instead, physicians at the four clinical testing sites gathered the donor stool themselves, and they were encapsulated on site by the testing facilities. Thus, in Phase 1b/2, Seres did not gather the healthy stool samples and did not manufacture the finished product.

46. CW1 was a senior executive in manufacturing and quality employed by Seres during the Class Period. When CW1 joined the Company, Seres had just completed the Phase 1b/2 clinical trial of SER-109 and was gearing up for Phase 2. CW1 reported to John Aunins, Chief Technology Officer. CW1 attended weekly leadership meetings with senior directors regarding Phase 2. CW1's responsibility was to oversee the quality control testing and authorization of the release of the SER-109 drug products for use in the Phase 2 trial. CW1 left Seres in July 2016, shortly before the release of the Phase 2 results.

47. CW1 explained a key manufacturing difference between Phase 1b/2 and Phase 2: In Phase 2, the SER-109 product was manufactured in-house by Seres; but in Phase 1b/2, the SER-109 product was not manufactured in-house; instead, the participating clinical sites collected

donor material themselves, which was processed and produced and turned into the final capsulized treatment by the clinical site facilities before being administered to patients.

48. Second, Phase 2 required Seres to create a "new formulation" of SER-109. *Id.* In cohort 1 of Phase 1b/2, the first 15 patients received SER-109 that was composed of spore dosages between $3x10^7$ and $2x10^{10}$. Cohort 1 patients received 15 doses per day for two days for a total of 30 doses. Cohort 2, the second 15 patients in Phase 1b/2, received SER-109 with a spore count of $1x10^8$. Cohort 2 patients received anywhere from ***1 to 12 doses*** of SER-109 each day. In Phase 2, however, the FDA required Seres to eliminate this variability in dosages and manufacture a version of SER-109 that was commercially viable. Thus, in preparation for Phase 2, Seres used a "new formulation" of SER-109, in a different capsule, that required only four doses, and contained the smallest spore count used in Phase 1b/2.

49. These changes were so significant that the FDA would not allow Seres to move immediately into Phase 3 testing. Instead, the FDA required Seres to "conduct a Phase 2 portion of the Phase 2/3 pivotal clinical trial to evaluate [the] new formulation of SER-109 before conducting the Phase 3 portion of the trial."[2] Accordingly, the FDA required Seres to conduct a Phase 2 trial to show safety and efficacy of the "new formulation" and to show that the Company could actually manufacture the drug as promised.

50. The SEC noticed these changes, and in a series of letters asked the Company to disclose them to investors as part of the Company's S-1. On June 5, 2015, the SEC wrote to Seres and noted that the "timing and stage of the clinical development plan for SER-109 have been substantially modified over the past 6 months" and asked Seres to explain why the plan had

[2] *See* Seres Health, Inc., SEC Letter Re: Amendment No. 2 to Draft Registration Statement on Form S-1, CIK No. 0001609809 (Apr. 29, 2015).

changed and disclose any "concerns expressed by the FDA" that led to the change of plans. Specifically, the SEC stated:

> We . . . note that the timing and stage of the clinical development plan for SER-109 have been substantially modified over the past 6 months and it is unclear from your disclosure what factors have caused you to modify this plan beyond your reference to discussions with the FDA. In this regard, investors are entitled to disclosure reflecting concerns expressed by the FDA where such concerns ***resulted in a material change to your clinical development program*** for your most-advanced product candidate and additional development costs. As such, with a view towards possible disclosure in the prospectus, please supplementally provide us with a discussion of any specific concerns or feedback you have received from the FDA relating to the clinical development of SER-109 and whether, and if so, how, the FDA's feedback led you to modify the clinical development program for SER-109.

51. On June 9, 2015, counsel for Seres responded to the SEC and explained that the SEC had directed Seres to "conduct [its] Phase 3 clinical trial using SER-109 product that is manufactured in a manner identical to the product that will be manufactured post-licensure" and that after further discussion with the FDA, the Company had decided "to commence a Phase 2 study while we developed the final manufacturing requirements and analytic assay validation that would have been required before we could start a Phase 3." Specifically, Seres's counsel wrote:

> We plan to conduct manufacturing pre-validation studies of SER-109 in the second half of 2015 to support a Phase 3 clinical trial and a potential biologics license application and commercial launch. <u>In doing so, we intend to satisfy the FDA's request that we conduct our Phase 3 clinical trial using SER-109 product that is manufactured in a manner identical to the product that will be manufactured post-licensure</u>. (emphasis in original).
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> <u>We initially proposed to the FDA a Phase 3 clinical trial and then a Phase 2/3 clinical trial, in each case in an effort to advance the clinical development of SER-109. However, in our subsequent interactions with the FDA, we determined that it would be more expedient to commence a Phase 2 study while we developed the final manufacturing requirements and analytic assay validation that would have been required before we could start a Phase 3 or combined Phase 2/3 clinical trial. Because the FDA cleared us to proceed with the Phase 2 clinical study, we were able to dose the first patient in this study in May 2015. We expect initial clinical study results in the middle of 2016</u>. (emphasis in original).

52. On June 15, 2015, the SEC again wrote to Seres:

> Please revise your disclosure in the prospectus summary to disclose that you have refined the formulation of the inner capsule and changed the manufacturing process for SER-109 to enable production to meet commercial requirements and that the manufacturing and formulation changes have resulted in a more pure form of SER-109. Please also note that you are conducting pre-validation studies to demonstrate the ability of the manufacturing process to inactivate and clear potential pathogens of concern as you indicate on page 103 of the prospectus. Please also disclose that the FDA has specifically requested that you evaluate your new formulation of SER-109 prior to commencing a Phase 3 clinical trial.

53. On June 22, 2015, Seres wrote back to the SEC and agreed to include new language addressing these changes, but Seres modified the SEC's proposed language in a critical respect. Seres did not merely tell investors that the SER-109 used in Phase 2 was "more pure" than the SER-109 used in Phase 1b/2. Seres also claimed that the new SER-109 was "***comparable in potency***." *See* Ex. B. As investors would later learn, this was not true.

54. Thus, heading into Phase 2, Seres was manufacturing a "new formulation" of SER-109, in a new capsule, and was, for the first time, manufacturing the drug in-house.

C. Seres Leverages the Phase 1b/2 Success to Raise $138 Million in its IPO

55. Despite these changes, Defendants presented an optimistic front, and just as they were staring Phase 2 trials, Seres completed its IPO. In the S-1, Seres used the above-quoted language regarding "comparable potency." The S-1 was deemed effective on June 25, 2015, the day before the Company's stock began trading on the NASDAQ stock market. Defendants told investors in the S-1, "We believe that the manufacturing formulation changes have resulted in a ***more pure form of SER-109*** that, based on pre-clinical studies, is ***comparable in potency*** to that used in the Phase 1b/2 clinical study." On February 25, 2016, during Seres's Q4 2015 earnings call with analysts and investors, Pomerantz described Seres's reformulated version of SER-109: "we have now released specs [i.e., to the FDA] for the final formulation approved, we're using in

Phase 2 the released specs and the analytics that will be the same formulation for launch. So no bridging studies."

56. The IPO was successful. Seres's common stock began trading on the NASDAQ stock market on June 26, 2015. The Company priced about 7.4 million shares at $18 each, beating its expected range of $15 to $17. According to an article in *The Boston Globe*, the IPO followed a "coast-to-coast roadshow" that began on June 16, 2016, with "presentations to analysts and sales executives at [the Company's] investment banks," Bank of America and Goldman Sachs.[3] Then, Seres executives traveled to Baltimore, New York, Boston, San Francisco, Denver, Kansas City, and Chicago – at each stop conducting a series of fast-paced meetings with investors. When trading began on June 26, 2016, "[t]he stock came out in the high $20s and kept moving higher. By the end of the day, Seres shares had almost tripled" from the original list-price of $18 to close at $51.40 – an increase of 285%.

D. Seres Initiates Phase 2 and Defendants Continue to Tout SER-109's Purity and Potency, and Phase 2's Probability of Success

57. On May 28, 2015, Seres announced that the first patient had been dosed in the Phase 2 clinical trial. The Company planned to include 87 patients in a double-blinded and placebo-controlled clinical trial, with patients randomized in a ratio of 2:1, SER-109 versus placebo. That is, for every one patient treated with placebo, two received SER-109. Ultimately, 59 patients received SER-109 and 30 received placebo – 89 patients in all. The primary endpoint of Phase 2 was the absence of CDI recurrence requiring antibiotic treatment during the eight-week follow-up period after receiving a single oral dose of SER-109.

[3] Steven Syre, "How a small drug maker enters market to soaring stock prices," *The Boston Globe* (July 28, 2015).

58. The S-1 described that Seres had "refined the formulation" of SER-109 and "changed the manufacturing process" for the Phase 2 study and that Seres's management "believe[d] that the manufacturing and formulation changes have resulted in a more pure form of SER-109 that is comparable in potency to that used in the Phase 1b/2 clinical study":

> *Phase 2 clinical study design*
>
> [P]atients will be randomized 2:1 to receive either a single oral dose of SER-109 in four capsules or a matching placebo in four capsules . . . . . In preparation for the clinical study, we have refined the formulation of the inner capsule and changed the manufacturing process to enable production to meet commercial requirements. We believe that the manufacturing and formulation changes have resulted in a ***more pure form of SER-109 that is comparable in potency*** to that used in the Phase 1b/2 clinical study based on a pre-clinical mouse *C. difficile* model.

59. The S-1 confirmed that, like the Phase 1b/2 study, the "primary efficacy objective in the Phase 2 clinical study will be to demonstrate the superiority of SER-109 compared to placebo in the prevention of recurrent CDI in adult patients up to eight weeks after treatment."

60. Following the IPO and the initiation of Phase 2, throughout the Class Period, Defendants touted the efficacy of reformulated SER-109, Seres's capability to manufacture it, and the high probability of success of Phase 2. As discussed in detail *infra* at ¶¶ 48-49, Defendants knew, however, that the SER-109 used in Phase 2 was not as potent as that used in Phase 1b/2 because the new formulation did not have the same number of spores. It was neither manufactured in the same place nor by the same people. It did not require the same dosages as Phase 1b/2. In short, it was a different pill. Similarly, despite their assurances to the contrary, the in-house manufacturing of SER-109 was not going as planned.

61. Seres's decision to begin manufacturing SER-109 itself added to the pressures within the Company. At the time of Phase 1b/2, Seres was a small start-up company, and during that study SER-109, the flagship product, was actually manufactured at the clinical testing sites. When Phase 2 began, Seres brought manufacturing in-house and in addition, began making

it on a commercial scale. These rapid changes within the Company led to a lack of quality control. Scientists working on the casing of the drug and the assays were working 16-hour days and were not comfortable with the deadlines set by management. This made it difficult for them ensure consistent quality of SER-109.

62. CW2 began working for Seres before Phase 2 was completed and held CW2's position until after Seres had announced the Phase 2 results. CW2 worked in the Quality Organization. According to CW2, Seres's Quality and Regulatory departments were "extremely weak and understaffed and also just didn't have the expertise they needed."

E. Defendants Learn as Early as February 2016 That Phase 2 Was Not Succeeding as Planned

63. During the Class Period, Defendants had access to results indicating that Phase 2 was not going as planned as early as February 2016. Three facts lead to this conclusion.

64. First, the unblinded "open label" extension arm of Phase 2 allowed Defendants to learn that more patients than expected were failing out early. In theory, the open-label arm was designed to let patients treated with the placebo get the real drug. But the testing protocol and the S-1 make clear that patients in either arm – placebo or SER-109 – could elect to take the extra dose of SER-109. The open label extension arm provided additional information to Defendants because Defendants knew when any patient had opted for another dose of SER-109.

65. The "open label extension study" is described in Seres's S-1 as follows:

> *Open label extension study.* Patients in either arm of the Phase 2 clinical study who relapse and experience an episode of recurrent CDI within eight weeks of treatment will be permitted to enroll in an open label extension study in which they will receive a single dose of SER-109. Participation in the open label extension will be conditioned upon the patient's continued satisfaction of the inclusion and exclusion criteria. We believe that providing the open label extension will assist in facilitating enrollment in the Phase 2 clinical study by providing participants the opportunity to ultimately receive SER-109 if they are initially enrolled in the placebo group. In addition, we believe the open label study will provide additional safety data and

> may provide us with greater understanding of the impact of a second dose of SER-109.

66. Once a patient opted to participate in the open label extension, by definition, Defendants knew: (a) the patient had failed the 8-week endpoint and (b), as results mounted, they knew that as a pure matter of statistics, more SER-109 patients were failing than expected. This allowed the Company to gather information about the success or failure of Phase 2 on a rolling basis. This is information the market was not privy to. Moreover, even for patients who did not enroll in the open label arm, when a patient failed the 8-week endpoint, Defendants knew that the patient was twice as likely to be a part of the SER-109 arm because the Phase 2 trial was randomized at a 2:1 ratio (i.e., two patients received SER-109 for every patient that received a placebo).

67. Second, not only was this information available, but Defendants were receiving it in real time. At the beginning of Phase 2, Seres hired medical monitors to oversee the trials at the various testing sites. The medical monitor informed participating physicians of the protocols, patient eligibility criteria, and approved patients for inclusion in the trials. Each clinical site had designated personnel, typically a research coordinator, who handled transmission of samples, reports, files, and data to Seres. The research coordinator would relay patient information and results by fax or email scans to Seres.

68. CW1, a senior executive in manufacturing and quality during the Class Period, confirmed that Defendant Trucksis would have received such updates and information regarding how the Phase 2 clinical study was going.

69. Because the endpoint of Phase 2 was to see whether patients relapsed with CDI, each participating patient had regular clinic visits. If the patient exhibited symptoms of CDI, the patient would come back to the clinic for an examination and stool test. There was constant

communication with Seres on specific protocols of Phase 2, and patient medical reports were kept synchronized between the trial site and the Company. Thus, if a patient relapsed before the 8-week endpoint, Seres was informed by the testing site of that relapse in real time and Seres would know that the patient had failed the endpoint. Similarly, if the patient enrolled in the open label extension, Seres would receive that information as well.

70. Lead Plaintiffs' consulting expert, Ms. Chew, confirmed that electronic synchronization of patient data between clinical trial sites and the company sponsoring the trial (here, Seres) has been industry standard practice for several years. The reason is simple – clinical trials of investigational new drugs are designed to track not only efficacy, but also safety. As just discussed, data concerning adverse events (such as an incidence of debilitating diarrhea) must be tracked closely in order to protect patients, and comply timely with FDA reporting requirements.

71. Third, and finally, almost all of the foregoing data was gathered, available, and communicated to Defendants by February 2016. The Phase 2 clinical trial was originally posted on Clinicaltrials.gov on May 6, 2015. At that time, Phase 2's "primary completion date" was "2016-03" (i.e., March of 2016). As of February 5, 2016, the Phase 2 protocol on Clinicaltrials.gov still stated that March 2016 was the anticipated "primary completion date." (No further changes were made to the protocol on Clinicaltrials.gov until May 16, 2016, when the protocol was changed to reflect a new "primary completion date" of June 2016).

72. Further, patients in Phase 2 experienced "a high rate of serious adverse events" and such events were "higher" in patients that took SER-109 than in patients that took a placebo. Under 21 CFR 312.64(b) "***An investigator must immediately report to the sponsor any serious adverse event, whether or not considered drug related***, including those listed in the protocol or investigator brochure and must include an assessment of whether there is a reasonable possibility

that the drug caused the event." Thus, Defendants received immediate notice of these frequent SAEs as they occurred throughout Phase 2. Not only did the Defendants receive notice, Ms. Chew states that Seres would have to determine the relatedness of the SAE (i.e., was the diarrhea related to SER-109), and report these findings and the presence of an SAE to the FDA.

73. Thus, by February 5, 2016, almost all of the patients needed to reach target enrollment had already enrolled. Otherwise, the trial protocol would have been updated to indicate a later anticipated completion date for the primary endpoint. It was not. Of the patients enrolled, almost all of them had reached their primary endpoint, and, as the public would later learn, the results were not good.

74. All told, 89 patients enrolled in Phase 2. Of those patients, 59 were given SER-109 and 30 were given placebo. 26 of the 59 SER-109 patients, or 44%, failed the primary endpoint and experienced a recurrence of CDI. 16 of the 30 placebo patients, or 53%, failed the primary endpoint and experienced a recurrence of CDI. Of the patients who experienced a recurrence, 34 enrolled in the open label study. That is, more patients enrolled in the open label extension than the total number of patients treated with placebo.

75. Defendants had most – if not all – of this data by February 2016. They knew approximately how many patients had failed the 8 week endpoint and they knew approximately how many patients had enrolled in the open label extension arm. As a result, Defendants could easily infer that Phase 2 was not going as planned.

F. Defendants Enter 10b5-1 Trading Plans, Continue to Promote Phase 2 and Sell Shares

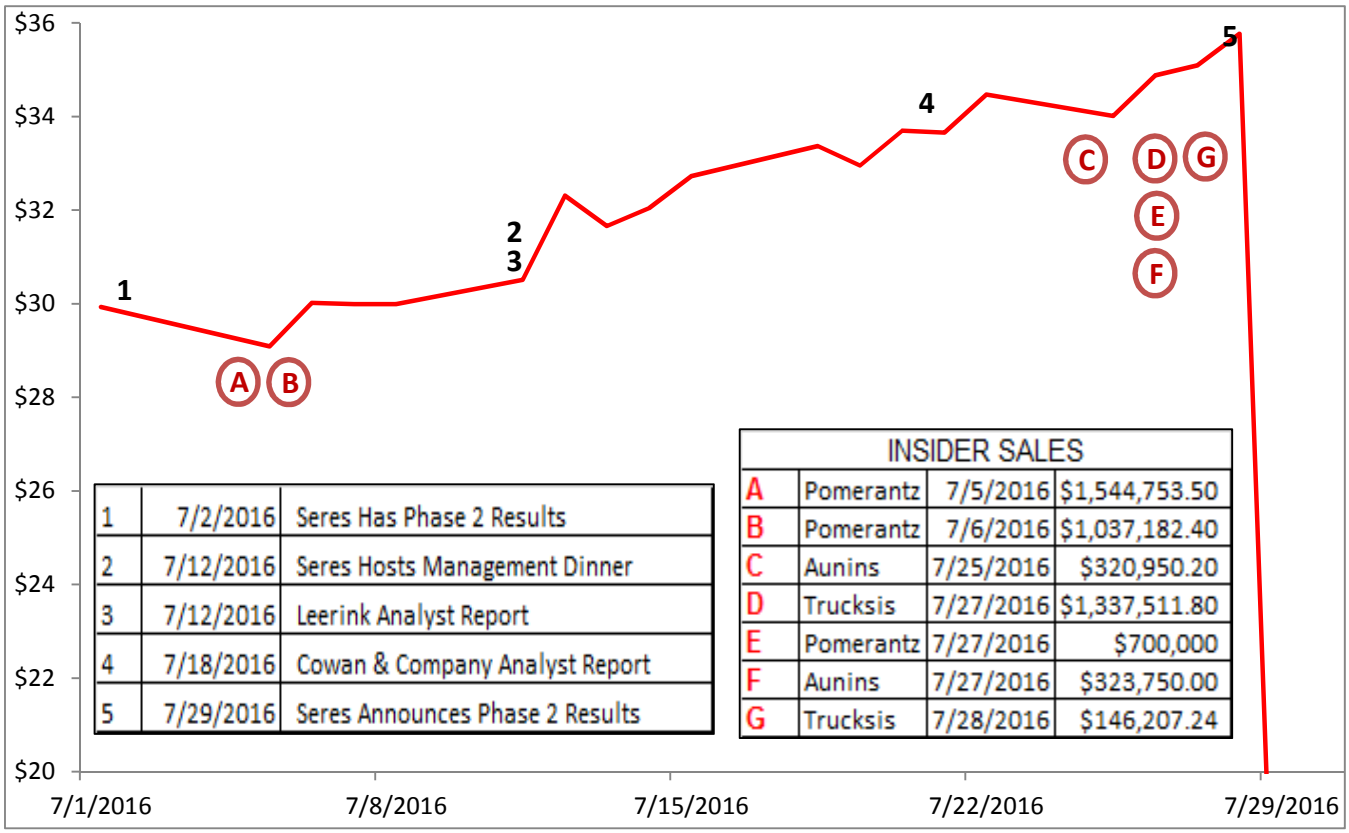
76. Armed with the foregoing information, rather than warning the market, Defendants Pomerantz and Trucksis, and insider Aunins (Seres's Chief Technology Officer and "Head of CMC"), entered into 10b5-1 trading plans in late February and late March 2016 so they could sell

their Seres shares and avoid heavy losses. All the while, they continued to lead the market to believe that Phase 2 would succeed just as Phase 1b/2 had. On May 2, 2016, Seres issued a press release announcing that it had enrolled the 89th patient in the Phase 2 clinical study of SER-109, and thereby achieved "target enrollment." At this point, all 89 patients had been enrolled and given a one-time oral dose of SER-109 or placebo. By July 2, 2016 (8 weeks later), the very last patient would have either failed the endpoint or completed the study successfully.

77. On or around July 12, 2016, Seres hosted a "Management Dinner" with analysts. Analysts from Leerink and Cowan and Company attended the Management Dinner. At the dinner, Seres management discussed the Phase 2 clinical study of SER-109. Following dinner, on July 12, 2016, Leerink published a report noting the "Dinner [with] Management," and stating that "[w]e met with [management] to discuss . . . [Phase 2] SER-109 ECOSPOR study" and that "[w]e remain positive on SER-109's ECOSPOR data." On July 18, 2016, Cowan and Company published a report titled "Takeaways from Management Dinner" stating that Cowan and Company had "Continued High Confidence in Upcoming [Phase 2b SER-109] C. Diff Data." Between July 12 and 28, 2016, Seres's stock price increased 10.7% – from a closing price of $32.31 per share on July 12, 2016, to a closing price of $35.77 per share on July 28, 2016. The stock price rose despite the fact that by at least July 2, 2016, Seres had full knowledge of Phase 2's failure.

78. Between July 2, 2016, and July 29, 2016, before Seres publicly revealed Phase 2's failure, Defendants Pomerantz and Trucksis and John Aunins collectively sold Seres stock for ***$5,425,951***. Of these sales, Pomerantz, Trucksis, and Aunins sold ***$2,507,527*** of stock on July 27 and July 28 – the two days before Phase 2's failure was announced. The following chart places Pomerantz, Trucksis, and Aunins's stock sales in the context of Seres's receipt of the results of Phase 2 (July 2, 2016), Seres's "Management Dinner" with analysts (July 12, 2016), analysts'

positive reports to investors, and the announcement of the surprising and disappointing results of Phase 2 and the resulting 72% stock drop.



G. Seres Announces that Phase 2 Had Failed

79. On July 29, 2016, at 7:00 a.m., Seres issued a press release announcing that the Phase 2 clinical trial of SER-109 administered as a single oral dose for the treatment of recurrent CDI did not achieve its primary endpoint when compared to a placebo. Significantly, SER-109 failed to prove that it was even marginally more effective than the placebo, i.e. no treatment at all. Even more surprising, for patients under 65, the placebo proved significantly more effective (27% relapse rate) in preventing recurrence of CDI than SER-109 (43% relapse rate).

H. Following the Class Period, Defendants State that "CMC" "Rose to the Top" as the Probable "Root Cause" of the Failure of Phase 2 and that Dosing in Phase 2 "May Have Been Suboptimal"

80. On August 11, 2016, during Seres's Q2 2016 earnings conference call, Defendant Pomerantz was asked why he thought Phase 2 had failed, and in response, stated: "There are many in our spreadsheet but the one that rose to the top are CMC as I said before."

81. Several months later, on January 31, 2017, Seres published a press release titled "Seres Therapeutics Announces Key Findings from SER-109 Phase 2 Study Analysis." In the press release, Seres admitted that rather than being "comparable in potency" to the SER-109 used in the Phase 1b/2, the dose of SER-109 used in Phase 2 may have been "suboptimal in certain patients" in light of the higher efficacy of the "higher dose" given to patients in Phase 1b/2. In other words, the SER-109 used in Phase 2 was not "comparable in potency" to that used in Phase 1b/2.

82. Ultimately, Defendants should not have been touting their CMC capabilities during the Class Period, because Seres was not ready to make a SER-109 that was both commercially viable and comparably effective as the SER-109 in Phase 1b/2, and it had not in fact done so when Defendants were inducing investors to believe that Phase 2 results would replicate those from Phase 1b/2. Nancy Chew's experience leads her to believe that CMC was a significant factor in Phase 2's failure.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD AND ANALYST AND MARKET REACTIONS THERETO

A. June 25, 2015 – Form S-1 Registration Statement

83. As discussed herein, on June 16, 2015, Seres filed an Amendment to a Form S-1 Registration Statement with the SEC announcing its IPO. The S-1 was deemed effective by the

SEC on June 25, 2015, the beginning of the Class Period. The S-1 touted the efficacy and outlook of Seres's lead drug candidate, SER-109, stating in relevant part:

> We initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. We expect study results in the middle of 2016. In preparation for the Phase 2 clinical study, we refined the formulation of the inner capsule and changed the manufacturing process for SER-109 to enable production to meet commercial requirements. ***We believe that the manufacturing and formulation changes have resulted in a more pure form of SER-109 that***, based on pre-clinical studies, ***is comparable in potency to that used in the Phase 1b/2 clinical study.***

84. The above statement made in the S-1 was materially false and misleading when made for the reasons articulated in Section IV, and because they led the market to believe that the form of SER-109 used in Phase 2 was "more pure," when in fact, it was not "comparable in potency" to the formulation of SER-109 used in the Phase 1b/2 study.

85. Consistent with these positive statements about the purity and potency of the reformulated SER-109 used in Phase 2, Seres stock increased from its initial price of $18 in the IPO to $51.40 at the end of closing on June 26, 2015, its first day of trading – ***an increase of 285%.***

B. August 20, 2015 – CNBC's Mad Money

86. On August 20, 2015, Defendant Pomerantz appeared on the television program *Mad Money*, hosted by Jim Cramer on the CNBC television network. During the program, Pomerantz stated as follows:

> [**Pomerantz**]: ***We saw clinical data that gives us ideas that this has a high probability of success.*** This is why Seres gets me so excited. This is what gets me out of bed in the morning, because we're able to not only treat infectious diseases, but chronic diseases that were not amenable to other therapies.
>
> ***
>
> [**Pomerantz**]: We understand the microbiome, as you said very rightly, as an ecosystem, like a forest or a coral reef. One bacteria not just doesn't work, it can't work. Now let me show you one of the things that's different is we don't just do cool science, we put a pill on the table. . . .

87. At this point in the interview, Pomerantz retrieved a pill bottle from his pocket, removed a capsule, and held it up for the television audience:

Seres Therapeutics CEO: Banking On Bacteria | Mad Money | CNBC

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> [**Pomerantz**]: [T]his is what I think makes Seres special as a biopharma. That is the first, we expect, microbiome drug. ***That has one times ten to the eighth bacteria in spore form in there and you take four of them once and that's how we cured 97% of people with CDI***, with c. diff. infection.
>
> [**Mad Money**]: Sir, you are doing amazing things. . . .

88. The above statements made by Defendant Pomerantz on *Mad Money* were materially false and misleading when made for the reasons articulated in Section IV, and because they led the market to believe that the reformulated SER-109 was the same drug that "cured 97% of people with CDI" in the Phase 1b/2 trial and had a "high probability of success," when in fact, the SER-109 used in Phase 2 had been reformulated, and, as a result, was less efficacious, less

potent, and therefore had a lower probability of success. In addition, Seres had been experiencing CMC problems after reformulating SER-109 and moving manufacturing in-house.

C. November 10, 2015 – Q3 2015 Earnings Conference Call

89. On November 10, 2015, Seres held its 2015 third-quarter earnings conference call with analysts and investors. During the conference call, Pomerantz responded to an analyst's question about Phase 2:

> [**Analyst**]: I was wondering if you could talk a little bit more about the Phase 2 trial design and goals for SER-109, and how does that extend from the experience that you generated in Phase 1b/2?
>
> [**Pomerantz**]: Sure, I'd love to answer that. So we first of all are pleased with where we are with the Phase 2 trial, its enrollment moving forward and 36 approximate centers across the United States and remain on track as I said, for the read out in mid-2016.
>
> When we think about a further Phase 3, we will have more guidance on the start and potential design of the Phase 3, after we analyze the Phase 2 data of course. But it's important to say that ***the Phase 2 trial that's going on is highly similar to what we've showed in the unprecedented data in Phase 1b/2***, the same group of patients, the main difference is that it's spread throughout the United States in both community and large centers, really as part of not only doing the trial as broad as possible, but also getting the word out of what a microbiome drug will look like. We think this accomplishes both and again, we expect to read out in mid-2016.

90. The above statements made by Pomerantz during the Q3 2015 earnings conference call were materially false and misleading when made for the reasons articulated in Section IV; for the reasons stated in ¶¶ 85, 89, above; and because they led the market to believe that Seres's capabilities in CMC and manufacturing gave the Phase 2 clinical study a high probability of success, when in fact, the reformulated SER-109 used in Phase 2 was less potent than in Phase 1b/2 and had a lower probability of success; Seres was experiencing CMC problems after reformulating SER-109 and moving manufacturing in-house; and data flowing from Phase 2, which was then available to Seres, already showed that the reformulated form of SER-109 was less effective at preventing recurrence of CDI in patients.

91. Analysts reacted favorably. In an analyst report published the same day, CANACCORD/Genuity stated, "Given that 13/15 patients (87%) had no C. difficile Infection at eight weeks, and 29/30 patients (97%) had clinical cure, ***we expect Phase 2 to be positive***."

D. January 13, 2016 – JPMorgan Healthcare Conference

92. On January 13, 2016, Defendant Pomerantz attended the JPMorgan Healthcare Conference with analysts and investors. During the conference, Pomerantz touted Seres's ability to manufacture SER-109 as a reason why Phase 2 had a high probability of success:

> So we do lead optimization. We then go to our CMC formulation group. They make a simple-to-use Tylenol-sized capsule in each of these drugs. It's really remarkable. And it has become very industrialized. As you see, we can move with alacrity to the next indication as we build the knowledge to make the [probability of success] substantial.
>
> ***
>
> ***Manufacturing, this is really important to us.*** This is what we do better than anybody. We have professionals there – John Aunins, who used to run the CMC at Merck Vaccine, allows us to make [SER-109] as a simple biologic that is novel, but uses proven approaches.
>
> ***
>
> This is something that we hold very tight to the chest and think is an enormous advantage. It is not just doing the science. It is making the drugs. This is the -- ***if you take anything home, this is what allows us to get into patients and do it properly and have a great [probability of success]***.

93. The above statements made by Pomerantz during the JPMorgan Healthcare Conference were materially false and misleading when made for the reasons articulated in Section IV; for the reasons stated in ¶¶ 85, 89, 91, above; and because they led the market to believe that Seres's capabilities in CMC and manufacturing gave the Phase 2 clinical study a high probability of success, when in fact, the reformulated SER-109 used in Phase 2 was less potent than in Phase 1b/2 and had a lower probability of success; Seres was experiencing CMC problems after reformulating SER-109 and moving manufacturing in-house; and data flowing from Phase 2,

which was then-available to Seres, already showed that the reformulated form of SER-109 was less effective at preventing recurrence of CDI in patients.

E. February 23, 2016 – VoiceAmerica Health & Wellness Program

94. On February 23, 2016, Defendant Trucksis appeared on "*C. diff.* Spores and More," a regular Internet radio program on the VoiceAmerica Health & Wellness channel.[4] The episode, titled "Ecobiotics- A Novel Approach to Recurrent C. difficile infections," was hosted by Nancy C. Caralla, the Founder & Executive Director of the *C. Diff.* Foundation. Trucksis appeared on the program with David C. Cook, Seres's Executive Vice President of R&D and Chief Scientific Officer.

95. During the program, Trucksis described the Results of the Phase 1b/2 study as "amazing" and "remarkable." Specifically, Trucksis said:

> [**Trucksis**]: So if you think about it overall, 29 of 30 patients then had no C. Diff. recurrence that would have required further antibiotic treatment in the eight weeks following dosing. And that's 96 percent of the patients in the study.
>
> [**Nancy Caralla**]: And that's –
>
> [**Trucksis**]: So – year. Isn't that amazing?
>
> ***
>
> [**Trucksis**]: So it was a pretty remarkable result.

96. Having touted the "amazing" and "remarkable" results of the Phase 1b/2 study, Trucksis proceeded to misleadingly describe how the Phase 2 study was "like the first study I told you about." Trucksis omitted, however, to state that the "single dose" of "four capsules" of "SER-109" that patients were administered in Phase 2 was not the same formulation or dose of "SER-109" that patients received in Phase 1b/2.

[4] *See* https://www.voiceamerica.com/episode/90635/ecobiotics-a-novel-approach-to-recurrent-c-difficile-infections.

> And ***like the first study*** I told you about that was published in the Journal of Infectious Disease, patients entering our Phase 2 study are on their third recurrence or greater of C. diff. Here they are treated with 14 to 21 days of standard of care antibiotics for C. diff and have their diarrhea respond to the antibiotic. And they are then dosed with a single dose, that's four capsules, of either SER-109 or placebo.

97. The above statements made by Trucksis during the VoiceAmerica Health & Wellness program were materially false and misleading when made for the reasons articulated in Section IV; for the reasons stated in ¶¶ 85, 89, 91, 94 above; and because they led the market to believe that Seres's capabilities in CMC and manufacturing gave the Phase 2 clinical study a high probability of success, when in fact, the reformulated SER-109 used in Phase 2 was less potent than in Phase 1b/2 and had a lower probability of success; Seres was experiencing CMC problems after reformulating SER-109 and moving manufacturing in-house; and data flowing from Phase 2, which was then-available to Seres, already showed that the reformulated form of SER-109 was less effective at preventing recurrence of CDI in patients.

98. Also during the February 23, 2016 VoiceAmerica Health & Wellness program, Trucksis repeatedly invited patients suffering from CDI to participate in the Phase 2 trial of SER-109:

> So if you're a patient listening to this, if in the past you've had really long courses of antibiotics and it didn't work, this time when you're coming in, you want to talk to one of our sites, and limit your therapy to ten to fourteen days, and then you'll be able to be included in our study. . . . . So we do try to include all the patients that we can include.
>
> ***
>
> And if a patient wants to participate in our clinical trial, I would just tell them to please go to either the website ClinicalTrials.gov, and search for Seres Therapeutics. They can also go to our website, serestherpeutics.com, and finally, Nancy, you have a link to our trials on your C. Diff. Foundation website. So these are all the ways that patients can find our trials ….

F. March 14, 2016 – 2015 Form 10-K

99. On March 14, 2016, Seres filed its Annual Report on Form 10-K for the 2015 fiscal year ended December 31, 2015 (the "2015 Form 10-K"). The 2015 Form 10-K emphasized that SER-109 used in Phase 2 was "a more pure form of SER-109 that is comparable in potency to that used in the Phase 1b/2 clinical study":

Phase 2 clinical study design

> The Phase 2 clinical study is a randomized, double-blinded, placebo-controlled, parallel-group trial with two treatment arms enrolling a total of 87 patients. We plan to enroll eligible patients at approximately 36 sites in the United States. Patients will be randomized 2:1 to receive either a single oral dose of SER-109 in four capsules or a matching placebo in four capsules. Based on the assumptions we have made for the recurrence rate of CDI and assuming we conduct final analyses for a minimum of 78 patients, our Phase 2 clinical study is sufficiently large, with the power of the study over 90%, to demonstrate that SER-109 is superior to placebo. The SER-109 formulation of the inner capsule has been refined to enable production to meet commercial requirements. We believe that the manufacturing and formulation changes have resulted in a ***more pure form of SER-109 that is comparable in potency to that used in the Phase 1b/2 clinical study*** based on a pre-clinical mouse C. difficile model.

100. The 2015 Form 10-K included certifications signed by Defendant Pomerantz, required under the Sarbanes-Oxley Act of 2002 ("SOX"), representing that he had reviewed the 2015 Form 10-K and that the 2015 Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

101. The above statements in the 2015 Form 10-K were materially false and misleading when made for the reasons articulated in Section IV; for the reasons stated in ¶¶ 85, 89, 91, 94, 98, above; and because they led the market to believe that Seres's capabilities in CMC and manufacturing gave the Phase 2 clinical study a high probability of success, when in fact, the reformulated SER-109 used in Phase 2 was less potent than in Phase 1b/2 and had a lower

probability of success; Seres was experiencing CMC problems after reformulating SER-109 and moving manufacturing in-house; and data flowing from Phase 2, which was then-available to Seres, already showed that the reformulated form of SER-109 was less effective at preventing recurrence of CDI in patients.

102. On May 15, 2016, Leerink published an analyst report noting that Seres had achieved target enrollment for Phase 2 and predicting a "high success rate" given the similarities and "high comparability" between the two studies:

> • **Bottom Line: Now that target enrollment has been achieved for the ECOSPOR [Phase 2] SER-109 study in recurrent [CDI patients], we look forward to a high response rate (80% +) being duplicated when data are reported in mid-2016.** (emphasis in original).
>
> ***
>
> • **Some adjustments are being implemented in [Phase 2], which is randomized and [placebo-controlled] (n=87) to assess the absence of [recurrent CDI] after 8 weeks.** (emphasis in original). The treated cohort is still receiving the same fixed dose (1x10^8 spores), but from a different set of donors. Aside from this nuance and the introduction of a [placebo] arm, ***the use of a similar study duration and efficacy endpoint facilitates high comparability to [Phase 1b/2] data and the likelihood of high success rate.***

103. Analysts continued to respond favorably. On May 27, 2016, CANACORD/Genuity published an analyst report stating:

> SER-109 rCDI Phase 2 readout expected positive, profile favorable to FMT and competition
>
> ***
>
> Phase 2 trial design should yield favorable response
>
> ***
>
> ***Differences vs. Phase 1/2 not an issue, expect success.*** The trial design of the Phase 2 is generally similar to that of the Phase 1b/2, with important differences that we believe will favor SER-109 highlighted below:

104. On June 6, 2016, Cowen and Company published an analyst report stating:

> We are initiating with an Outperform rating on MCRB, with high confidence of success in the very near-term Ph2 data of lead microbiome candidate SER-109 in prevention of multiply recurrent C. Diff infection.
>
> ***
>
> **We Believe Lead Drug SER-109 Has An Excellent Chance of Success In Its Current Ph2 Trial For Prevention Of Multiply Recurrent CDI** (emphasis in original).
>
> SER-109 is [Seres's] microbiome-based drug for prevention of multiply recurrent C. Diff infection. We think the fully enrolled ongoing placebo controlled [Phase 2 SER-109] trial has a very high (>70%) chance of success given good powering (92% powered to show a 80% [SER-109] response rate vs [placebo]) and excellent pilot trial precedent data.
>
> ***
>
> [w]e see the current SER-109 Ph2 trial as having a very high chance of success in the imminent future.

105. Consistent with Defendant Pomerantz's positive statements regarding SER-109 and Seres's CMC capabilities, and analysts' positive reactions to those statements, Seres's stock increased from an opening price of $23.99 on May 16, 2016, to a closing price of $30.43 on May 31, 2016 – an increase of approximately 27%. Seres's stock price never again dropped below $29.00 per share until the end of the Class Period.

G. June 7, 2016 – Goldman Sachs Global Healthcare Conference

106. On June 7, 2016, Defendant Pomerantz attended the Goldman Sachs Global Healthcare Conference with analysts and investors. During the conference, Pomerantz downplayed the changes made to SER-109 in Phase 2:

> [**Analyst**]: [T]he other question we get a lot is just as you think about similarities, differences between the first Phase II in the ongoing Phase II, maybe just give us some context there and how to think about [probably] success based on those similarities and differences.
>
> [**Pomerantz**]: Great. That's very important and, the first, remember was an open label of 30 patients, that the primary endpoint is exactly the same. In [1b/2] -- in this Phase [II/IIb] and in a Phase III, it will be no recurrence within eight weeks. The FDA agrees with this. The reason is if you look at the ID literature, if you're

> going to recur with C. diff, you recur within eight weeks. So, the primary endpoint is the same, big similarity, the same patient population for the most part in 1b/2 and II, they had to make multiple recurrences.
>
> So, one occurrence and two recurrences, and ***the changes that were made in the trial*** have -- ***were minimal***. One is ***the drug is a little purer and more concentrated***. Most importantly, we decided to do this as a company because I didn't want to have a bridging or a bioequivalence study needed before launch. I've had that with a drug I launched in the past and you don't want that. So, now we have in the space to the launch prep with the launch specs. So, there will be no bridging. It would be the same in Phase III, same in launch. So, we [need] that change.

107. The above statements were also materially false and were materially false and misleading when made for the reasons articulated in Section IV; for the reasons stated in ¶¶ 85, 89, 91, 94, 98, 102, above; and because they led the market to believe that the changes made to the SER-109 product used in Phase 2 were "minimal," when in fact, the reformulated SER-109 used in Phase 2 was less potent than in Phase 1b/2 and had a lower probability of success; Seres was experiencing CMC problems after reformulating SER-109 and moving manufacturing in-house; and data flowing from Phase 2, which was then-available to Seres, already showed that the reformulated form of SER-109 was less effective at preventing recurrence of CDI in patients.

H. July 12, 2016 – "Management Dinner" with Analysts

108. On or about July 12, 2016, Seres held a "Management Dinner" at which the Company's executives met with analysts, including analysts at Leerink and Cowan and Company to discuss, among other things, the Phase 2 clinical study of SER-109.

109. Following the Management Dinner, these analysts published several reports stating that "We remain positive on SER-109's [Phase 2] data" and that they had "Continued High Confidence in Upcoming [Phase 2b SER-109] C. Diff Data."

110. On July 12, 2016, Leerink published an analyst report stating that they had "met with" Seres's management to discuss the Phase 2 study of SER-109 and that they "remain[ed] positive" on data that would come out of Phase 2:

Dinner [with] [Management] Highlights Multiple Programs Germinating at [Seres]

• **Bottom Line: We met with [management] to discuss a range of topics including [Phase 2] SER-109 ECOSPOR study, pharmacoeconomics of SER-109, pipeline candidates (eg. SER-287 and SER-262), and the evolving regulatory landscape regarding microbiome therapeutics, among others. We remain positive on SER-109's ECOSPOR data . . . and await next updates from SER-287 (1H17) and SER-262. Reiterate [Outperform] on [Seres] with $43 [price target].** (emphasis in original).

•**Recurrence over 8 weeks is an endpoint agreed by the FDA.** (emphasis in original). Literature shows ~98% of recurrence happens within 8 weeks, which underscores the criticality of this time period. [Management] disclosed that the same primary endpoint will be adopted in a future [Phase 3] study whose specifics will remain unknown until after ECOSPOR data,

• [Seres's] proprietary research suggests SER-109 price tag of [$10,000 per patient] should be supportive.

***

• [Seres] has maintained an amicable relationship with FDA/EMA by abiding by regulator requests and substantiating with data.

111. On July 18, 2016, Cowan and Company published an analyst report stating that they had attended a "Management Dinner" with Seres. Based on "last week's discussion with [Seres] management," the report stated that "We Continue To See High Probability of Success For [Phase 2] SER-109 Data Readout in Late July/Early August" and that "We think the fully enrolled ongoing placebo controlled [Phase 2 SER-109] trial has a very high (>70%) chance of success":

Takeaways From Management Dinner:
[Phase 2 SER-109] Data in Late July/Early August

The Cowen Insight

We have high confidence in upcoming [Phase 2] data of lead microbiome candidate SER109 in prevention of multiply recurrent C. Diff (expected late July/early August), ***based on strong precedent data and trial design*** (discussed at the event). We do not see FMT as a viable competitor to [SER-109] . . . due to CMC, logistics, liability, and feasibility issues. We model $535M in peak US sales for [SER-109].

> **Continued High Confidence in Upcoming [Phase 2b SER-109] C. Diff Data Late July/August and Limited True Competition As Pipeline Progresses** (emphasis in original).
>
> ■ **Key Takeaways from Investor Dinner With [Seres Management] Last Week: We Continue To See High Probability of Success For [Phase 2] SER-109 Data Readout in Late July/Early August** (emphasis in original).
>
> ***
>
> We think the fully enrolled ongoing placebo controlled [Phase 2 SER-109] trial has a very high (>70%) chance of success given good powering (92% powered to show a 80% Ser-109 response rate vs 40% PBO rate). . . . . We would expect a minimum absolute separation of ~20% between groups for clinical meaningfulness, and believe the final rate will [prove] to [be] meaningfully higher.
>
> ***
>
> ***Given the rigor of the trial and precedent data we think there is high likelihood of success.***

112. Thus, during the "Management Dinner," Seres management gave the analysts "high confidence" that Phase 2 would be a success. Seres management's statements to analysts at this meeting were materially false and misleading when made because they touted Phase 2 when management already knew that the study had failed to meet its primary endpoint. Moreover, Defendants failed to disclose that the formulation of SER-109 used in Phase 2 was less potent than that given to many patients in Phase 1b/2, and that Seres had been experiencing CMC problems after reformulating SER-109 and moving manufacturing in-house.

113. Consistent with the positive reports written by the analysts that attended the "Management Meeting," Seres's stock price increased 10.7% from a closing price of $32.31 per share on July 12, 2016, to a closing price of $35.77 per share on July 28, 2016.

114. On July 29, 2016 – before Seres announced the failure of Phase 2 – H.C. Wainwright & Co. published an analyst report initiating coverage of Seres, and predicting positive results for SER-109 based on, among other things, Seres management's "confiden[ce] that the

manufacturing and formulation changes have resulted in a more pure form of SER-109 that is comparable in potency to that used in the Phase 1b/2 clinical study":

> **Good Microbes Can Conquer Disease; Assuming Coverage With a $50 12-Month Price Target**
>
> **We expect positive Phase 2 results with SER-109 for treatment of recurrent Clostridium difficile infection (rCDI) in 3Q16.** (emphasis in original). SER-109 is composed of ~50 species of Firmicutes spores derived from stool specimens from healthy donors. Seres was able to show in a Phase 1b/2 open label 30 patient rCDI trial a 97% cure of the infection. The company expects the 89 patient Phase 2 to show a ~80% response in the SER-109 arm vs. a 40% response in the placebo arm, which has over 90% power to detect a difference. We expect SER-109 to potentially generate ~$500M in worldwide sales in 2025.
>
> ***
>
> The SER-109 formulation of the inner capsule in this trial was refined to enable production to meet commercial requirements.
>
> ***
>
> ***Management is confident that the manufacturing and formulation changes have resulted in a more pure form of SER-109 that is comparable in potency to that used in the Phase 1b/2 clinical study*** based on a pre-clinical mouse C. difficile model.

VI. THE TRUTH EMERGES

115. On July 29, 2016, at 7:00 a.m., Seres issued a press release announcing that the Phase 2 clinical trial of SER-109 had not achieved its primary endpoint when compared to a placebo. Significantly, SER-109 failed to prove that it was even marginally more effective than the placebo, i.e., no treatment at all. In fact, for the group of patients under 65, ***the placebo greatly outperformed SER-109 in preventing the recurrence of CDI***.

116. The Company's press release stated in pertinent part:

> CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 29, 2016-- Seres Therapeutics, Inc. (NASDAQ:MCRB), a leading microbiome therapeutics company, today announced interim 8-week results from the ongoing SER-109 Phase 2 ECOSPORTM clinical study for the prevention of multiply recurrent Clostridium Difficile infection (CDI). ***The study's primary endpoint of reducing the relative***

risk of CDI recurrence at up to 8-weeks was not achieved. Seres continues to gather and analyze study data, and in consultation with the FDA, plans to make appropriate adjustments to its SER-109 development plans.

Study Design and Results

- Study Design: The Phase 2 study enrolled 89 subjects with multiply recurrent CDI, defined as 3 or more recent recurrences, in a randomized, double-blind, placebo-controlled 24-week study conducted to evaluate the safety and efficacy of SER-109. Subjects were randomized at a 2:1 ratio with 59 subjects receiving SER-109 and 30 subjects receiving placebo. SER-109 was administered orally as a single dose, of 1 X 108 bacterial spores, following the completion of antibiotic treatment for CDI. The study was conducted at 36 centers across the United States. Reported interim results reflect the available eight-week study data, including the primary efficacy endpoint, for the intent-to-treat study population.

- Summary of Efficacy: The predefined study primary efficacy endpoint is the relative risk of CDI recurrence up to 8 weeks after treatment comparing subjects in the placebo arm with the SER-109 arm. CDI recurrence is defined as diarrhea for 2 or more consecutive days, a positive CDI test, and the requirement for antibiotic treatment. Based on 8-week data, CDI recurrence occurred in 44% of subjects (26 of 59) who received SER-109, compared to 53% of subjects (16 of 30) who received placebo. ***The relative risk of CDI recurrence for the placebo population compared to the SER-109 population was not statistically significant.*** As part of the prespecified design, subjects were stratified into two groups: <65 years old and ≥65 years old. In subjects <65 years old, CDI recurrence occurred in 43% of subjects who received SER-109 (12 of 28) and in 27% of subjects who received placebo (4 of 15). In subjects ≥65 years old, CDI recurrence occurred in 45% of subjects who received SER-109 (14 of 31), and in 80% of those who received placebo (12 of 15).

- Summary of Safety: Based on the eight-week data, we did not observe any difference in the adverse event frequency or type in the subjects receiving SER-109 compared to those receiving placebo. The most commonly reported adverse events in both the SER-109 and placebo arms were in the gastrointestinal category. The most common adverse events reported in the SER-109 arm were diarrhea, abdominal pain and flatulence. No drug-related serious adverse events were observed.

117. Analysts were surprised and disappointed at the failure of Phase 2 to meet its endpoint. On July 29, 2016, at 7:58 a.m., Leerink published a "FLASH NOTE" stating:

Disappointing ECOSPOR Data Warrants Taking a Second Look at Microbiome

• Bottom Line: A [Phase 2] ECOSPOR trial investigating the first microbiome drug - SER-109 - in recurrent *Clostridium difficile* infection (rCDI) failed to meet [statistical significance] on its pre-defined primary endpoint of relative CDI risk up to 8 weeks post-treatment. As a lead drug candidate that

previously showed stunning results in [Phase 1b], the interpretation of today's data is negative, and could raise more caution on [Seres's] remaining platform. Our model is under review. (emphasis in original).

• ***Contrary to our (LINK) and [management's] expectations, there was no discernible improvement in SER-109 arm vs. [placebo]***. Up to 8 weeks after treatment, CDI recurrence occurred in 44% of SER-109 (26 of 59) vs. 53% of pbo. (16 of 30), and the delta in relative risk did not reach stat. sig. A sub-group analysis by age also failed to provide any clear evidence of efficacy as <65 age group favored pbo. (43% in SER-109 vs. 27% pbo.) whereas ≥65 age group favored SER-109 (45% in SER-109 vs. 80% pbo.) when assessed for recurrence.

• **[Phase 1b] efficacy that surprised the Street was unfortunately not reproduced.** (emphasis in original). Recall, [Phase 1b] was not [placebo]-controlled but SER-109 had achieved a responder rate of ~87% (no C. difficile-positive diarrhea up to 8 weeks post-dose) with ~97% of pts. eventually deemed clinically resolved. Coming into today's announcement, investors were cautious regarding the minor change in study design (e.g., addition of Abxtreatment regimen at baseline) as well as the potential read-through to a first pbo.-controlled trial from Ph. 1b. ***[Management] at our recent dinner had downplayed any such concern, reiterating its conservative powering assumptions*** (92% powered for 80% responder rate in SER-109 vs. 40% pbo.; LINK).

• **[Seres] shares likely to trade significantly lower on this news; our model is under review.** (emphasis in original). We had assigned 80% probability of success (PoS) to SER-109 along with 33% PoS for SER-262 in primary C. diff infection. Given its lead candidate status and the novelty of microbiome/ live biotherapeutic approach, the downside move could be amplified. With today's data, our model is under review and we expect investors will grow more cautious on not just SER-109 (and the C. diff franchise), but the entire microbiome platform.

• **Nevertheless, we will look for more clarity on the upcoming [conference call] at 8:30 A.M.** (emphasis in original). On the [conference call], we will be interested in the interpretations and reasons behind the surprise miss, the potential read-through to other microbiome programs within [Seres], and [management's] strategies to improve on today's weakness.

118. As a result of the announcement of the failure of the Phase 2 clinical trial of SER-109, the price of Seres common stock declined from a closing share price of $35.77 on July 28, 2016 to close at $9.73 per share on August 1, 2016, a loss of ***72%***, on extremely heavy trading volume.

119. On August 11, 2016, Seres held its 2016 second quarter earnings conference call with analysts and investors. During the conference call, Pomerantz stated:

> [**Pomerantz**]: Regarding the Phase 2 SER-109 drug product, ***a few manufacturing and formulation modifications were implemented prior to the study*** to purify and concentrate SER-109 bacterial spore. We are now seeking to ascertain if any of these changes had an adverse impact on drug products. We will carefully examine each step of the CMC process as well as the final Phase 2 SER-109 drug product.
>
> ***
>
> [**Analyst**]: Got it. And just one quick related follow up. In discussing the root cause, you mentioned CMC microbiome execution and translational, can you clarify what the translational investigation is . . . .
>
> [**Pomerantz**]: Yes, translational is just if you need animal modeling, that's usually what we consider translational science, there's other thing, so it is a soup to nuts root cause analysis. Just like how you design a drug and get -- and develop a drug, that's how you look at a root cause. And so we have all parts of the company looking at this. As I've said before certain things rise closer to the surface even though we have a long list of root cause possibilities, ***clearly CMC study design and diagnosis are on our top list at this point.***
>
> ***
>
> [**Analyst**]: Hey, Roger, good morning. Thanks for taking the question. I had one just on the sort of looking back on maybe some of the modifications that were made on SER-109 production. And I'm guessing and I don't know how much detail you really want to provide at this point in time. But I'm assuming that it's really perhaps a question of potency, if not maybe if you could correct me on that. But I guess my question, one is, I understand wanting to go back and look at the material perhaps that people were dosed with, but I mean can you not just fast forward to looking at the patient samples to see what kind of --
>
> [**Pomerantz**]: Yes. It's a great question. And I can answer some of it. So just to remind everyone, the main changes were just on increased concentration, increased purity, went from 15 to 30 capsules to four, all the release specs that we worked out with FDA looked good. ***But clearly when something has a problem in Phase 2, you always look at CMC.*** We are looking at it. We are looking both at the drug in comparison but also as you point out looking at the effects on the microbiome. We have patient samples from every patient before, during and after therapy. We will measure their microbiome using 16S ribosomal as well as shotgun sequencing for full genome amounts. That will help tell us as well how well the CMC new product work because we do have a comparator in [Phase 1b] where we know the microbiome of each of those 30 patients.

***

> [**Analyst**]: Thanks very much. Now that you've had some time to regroup after reporting the top line results. I was wondering if you could walk us through the general hierarchy of hypothesis you will be testing to determine the root cause of the surprising results of ECOSPOR? And how much data do you have on hand already versus do you need to collect from the sites? What parts of this exercise will take the shortest versus the longest? And then what is your philosophy for balancing rapid versus thoughtful communications to the Street? If you see something jump out from the earlier analysis of the data you have on hand, will you wait until every potential piece of information you can obtain has been processed or is there the possibility that you might communicate something that looks provocative along the way. Thank you.
>
> [**Pomerantz**]: Yes. Thanks for the question, Joe. I hate to speculate. What I like to do and what the company is doing is setting up hypothesis. We've talked about some of them already. There are many in our spreadsheet but ***the one that rose to the top are CMC as I said before . . . .***

120. On January 31, 2017, Seres published a press release titled "Seres Therapeutics Announces Key Findings from SER-109 Phase 2 Study Analysis." In the press release, Seres admitted that rather than being "comparable in potency" to the SER-109 used in the Phase 1b/2, the dose of SER-109 used in Phase 2 may have been "suboptimal in certain patients" in light of the higher efficacy of the "higher dose" given to patients in Phase 1b/2. Specifically, the press release stated that the "subjects in the [Phase 1b/2] study who received a higher dose achieved a significantly greater increase in diversity of commensal spore-former bacteria by 1 week post-treatment, as compared to both Phase 1b and Phase 2 subjects treated with lower doses. These results suggest that the dose used in the [Phase 2] study may have been suboptimal in certain patients, and may have resulted in a less robust drug effect, contributing to decreased efficacy in Phase 2, as compared to [Phase 1b/2]."

121. This admission comes in stark contrast to Defendants' repeated claims, during the Class Period, that the formulation of SER-109 used in Phase 2 was "more pure" and "comparable in potency to that used in the Phase 1b/2 clinical study."

122. On January 31, 2017, Seres held a conference call with analysts and investors at which Defendant Pomerantz admitted that patients in Phase 2 experienced "a high rate of serious adverse events" and that such events were "higher" in patients that took SER-109 than in patients that took a placebo. Specifically, Pomerantz stated: "The Phase 2 study population contained older individuals, many in poor health and a high rate of serious adverse events were reported in both study arms. A numerically higher rate of SAEs was observed in the SER-109 arm."

VII. ADDITIONAL ALLEGATIONS SUPPORTING THE DEFENDANTS' SCIENTER

123. Throughout the Class Period, Defendants knew that the prospects for a successful Phase 2 trial were not nearly as strong as the Company led on, in direct contradiction to Defendants' public statements. Defendants' scienter is supported by: (1) Defendants' suspiciously-timed insider sales during the Class Period; (2) the fact that SER-109 is the Company's lead product; (3) the fact that CMC is a core competency of the Company; (4) the small size of the Company; (5) and Defendants' SOX certifications. Finally, the cumulative knowledge of Seres personnel acting within the scope of their employment creates a strong inference of scienter that is imputed to the Company.

A. The Individual Defendants' Insider Sales During the Class Period Further Support a Strong Inference of Their Scienter

1. During the Class Period, the Individual Defendants and Other Seres Insiders Together Reap Almost $24.5 Million in Insider Trading Proceeds

124. During the Class Period, Defendants Pomerantz, Trucksis, and other Company insiders were unloading large numbers of Seres stock.

125. During the Class Period, Defendant Pomerantz sold 600,000 shares of Seres stock for proceeds of $17,517,354, all while in possession of material non-public information and while the price of Seres's stock was artificially inflated. Pomerantz sold shares fifteen times in the

months of April, May, June, and July 2016 – leading up to the July 29, 2016 announcement. Pomerantz's sales were unusual in timing and amount, especially considering that he has not sold a single share since the Phase 2 announcement.

126. Defendant Trucksis, the executive responsible for overseeing SER-109's clinical development, sold 42,220 shares of stock during the Class Period for proceeds of $1,483,777. The results of the trial would have gone directly to Trucksis first – making it all the more suspicious that she sold stock for the first and only time two days before the failure of Phase 2 was announced. Since Trucksis was the individual receiving the rolling trial data from the clinical sites, it is suspicious that both she and Pomerantz created 10b5-1 plans on the same date – February 26, 2016 – which allowed for the sale of millions of shares in the proceeding months leading up to the announcement of Phase 2's failure.

127. During the Class Period, other high-ranking Company executives, besides Pomerantz and Trucksis, also sold an additional 192,313 shares of Seres stock for total proceeds of $5,518.918. For example, Seres's EVP and CFO, Eric Shaff, sold 29,238 shares of Seres stock for proceeds of $798,141. Seres's Chief Technology Officer and Executive Vice President, John G. Aunins, who was the head of the CMC department, sold 70,075 shares of stock during the Class Period for proceeds of $2,141,166. Seres's Chief Scientific Officer and Executive Vice President, David N. Cook, sold 93,000 shares of stock during the Class Period for proceeds of $2,579,611.

128. A chart reflecting Seres executives insider trades is below:

Filer Name	Title	Date	Shares	Price	Proceeds
Roger Pomerantz	President, CEO	27-Jul-2016	20,000	$35.00	$700,000
		06-Jul-2016	25,535	$29.80	$760,943
		06-Jul-2016	9,900	$29.27	$289,773
		05-Jul-2016	49,871	$29.27	$1,459,724
		05-Jul-2016	2,905	$29.96	$87,034
		01-Jul-2016	4,832	$29.12	$140,708
		01-Jul-2016	41,957	$29.84	$1,251,997

		01-Jul-2016	10,000	$30.00	$300,000
		02-Jun-2016	6,583	$31.62	$208,154
		02-Jun-2016	47,159	$32.34	$1,525,122
		02-Jun-2016	20,307	$33.22	$674,599
		01-Jun-2016	18,510	$30.12	$557,521
		01-Jun-2016	52,441	$30.65	$1,607,317
		24-May-2016	9,801	$30.00	$294,030
		06-May-2016	8,199	$24.28	$199,072
		06-May-2016	308	$25.10	$7,730
		05-May-2016	21,127	$25.48	$538,316
		05-May-2016	8,900	$26.34	$234,426
		04-May-2016	28,598	$26.52	$758,419
		04-May-2016	700	$27.31	$19,117
		03-May-2016	16,338	$27.80	$454,196
		03-May-2016	7,142	$28.44	$203,118
		03-May-2016	200	$29.32	$5,864
		02-May-2016	35,438	$28.95	$1,025,930
		02-May-2016	8,249	$29.59	$244,088
		07-Apr-2016	9,212	$30.00	$276,360
		04-Apr-2016	15,203	$28.17	$428,269
		04-Apr-2016	22,418	$29.18	$654,157
		04-Apr-2016	6,416	$29.68	$190,427
		04-Apr-2016	788	$30.00	$23,640
		01-Apr-2016	40,506	$25.69	$1,040,599
		01-Apr-2016	38,080	$26.67	$1,015,594
		01-Apr-2016	12,377	$27.56	$341,110
Eric D. Shaff	Executive VP, CFO	30-Jun-2016	4,533	$29.54	$133,905
		28-Jun-2016	1,667	$28.85	$48,093
		27-Jun-2016	3,334	$28.00	$93,352
		04-Apr-2016	6,568	$28.85	$189,487
		31-Mar-2016	6,568	$26.50	$174,052
		31-Mar-2016	1,095	$25.13	$27,517
		28-Mar-2016	5,473	$24.07	$131,735
Michele Trucksis	Chief Medical Officer, EVP	28-Jul-2016	4,156	$35.18	$146,208
		27-Jul-2016	38,064	$35.14	$1,337,569
John G. Aunins	Chief Technology Officer , EVP				
		27-Jul-2016	9,250	$35.00	$323,750
		25-Jul-2016	9,390	$34.18	$320,950
		27-Jun-2016	9,390	$27.23	$255,690
		31-May-2016	650	$30.57	$19,870
		31-May-2016	13,365	$30.02	$401,217
		25-Apr-2016	18,640	$31.94	$595,362

		28-Mar-2016	9,390	$23.89	$224,327
David N. Cook	Chief Scientific Officer, EVP	02-Jun-2016	8,000	$31.00	$248,000
		01-Jun-2016	16,000	$29.43	$470,880
		07-Apr-2016	8,000	$31.00	$248,000
		04-Apr-2016	8,000	$28.00	$224,000
		01-Apr-2016	46,650	$25.74	$1,200,771
		01-Apr-2016	6,350	$29.60	$187,960
Total					***$24,520,049***

2. Trades During the Class Period Made Pursuant to 10b5-1 Plans Are Not Insulated from Scrutiny

129. That all of Pomerantz's and Trucksis' stock sales were made pursuant to a 10b5-1 trading plan does not insulate them from scrutiny. In 2000, the SEC adopted Rule 10b5-1, 17 C.F.R. § 240.10b5-1, which provides that a person will be deemed to have traded "on the basis of" material, nonpublic information if the person engaging in the transaction was "aware of" that information at the time of the trade.

130. The SEC also created an affirmative defense to insider trading claims for trades made pursuant to a binding agreement or plan. Pursuant to SEC Rule 10b5-1(c), a 10b5-1 plan is a potential (but not an absolute) defense to accusations of insider trading only if it is entered into by an insider "before becoming aware" of inside information and was established "in good faith and not as part of a plan or scheme to evade the prohibitions" against insider trading.

131. Because of this, insiders are advised to "design a trading plan with the intention that it will not be modified or amended frequently, since changes to the plan will raise issues as to a person's good faith."[5] Conversely, the adoption and/or modification of these plans while in possession of material, non-public information is highly suspicious and supportive of scienter.

[5] Thomas J. Griffith, *Corporate Counsel's Guide to Insider Trading and Reporting* § 12:26 (2015).

132. Even if Pomerantz and Trucksis could demonstrate that their stock sales were not irregular (and they cannot), 10b5-1 plans have been heavily scrutinized by the SEC in light of an eye-opening investigation by *The Wall Street Journal* that found that insiders who were selling pursuant to such plans still were selling at opportune times and reaping better-than-expected results. According to the article, executives still can time their stock sales to avoid losses and increase earnings because trading plans are not public and can be canceled or amended at any time without disclosure.[6]

133. Finally, although Pomerantz and Trucksis filed Form 4 reports with the SEC disclosing their trades and indicating that certain of them were made pursuant to 10b5-1 plans, no further information is available on the plans, with the exception that their plans were created on February 26, 2016 – a little over a month before Pomerantz's first stock sales. Without discovery, investors cannot understand the details pertaining to these plans' creation and amendments, whether any trades pursuant to the plans were canceled, or what criteria, such as share price, may have triggered sales pursuant to the plans.

3. Seres Insiders' July Stock Sales Are Particularly Suspicious

134. Seres would have been getting continuous reports of critical trial data as early as May 28, 2015, when the first patient was dosed, and up to July 2, 2015, eight weeks after the Company's achievement of target enrollment of SER-109 Phase 2 study. As discussed in Section IV, the Company would be receiving synchronized reports of adverse events and of patients entering into the open label study, signifying a reoccurrence of CDI. This backdrop makes the Seres insiders' July stock sales all the more suspicious.

[6] *See* Susan Pulliam & Rob Barry, *Executives' Good Luck in Trading Own Stock*, Wall St. J., Nov. 27, 2012, http://www.wsj.com/articles/SB10000872396390444100404577641463717344178.

135. In July 2016, Pomerantz sold 165,000 shares for total proceeds of $4,990,179. Trucksis made her only two sales since the IPO in the two days leading up to the July 29, 2016 announcement – selling 42,220 shares for total proceeds of $1,483,777. Aunins sold 18,640 shares in the four days leading up to the announcement – for total proceeds of $644,700. It is plausible to infer that these insiders had information about the failed Phase 2 trial during this time.

136. The media took notice of the suspicious nature of these trades, depicted in the chart below. As Statnews.com reported, "in the two days before [the failure of SER-109] became public, three top Seres executives sold a combined $2.5 million worth of the company's stock. They made a tidy profit. They avoided nearly $2 million in paper losses."[7] Furthermore, an article by *TheStreet* titled "Seres Plunges on Microbiome Drug Fail, Execs Profit on Insider Sales," noted that Pomerantz "netted almost $700,000 from the sale of company stock on Wednesday before the negative study results were announced caused the share price to plunge. Two other Seres executives also sold company stock on the same day." For a visual timeline, see the chart set forth in Section IV, which depicts Defendants' stock sales in connection with the events leading up to the Phase 2 results announcement.

137. For those reasons, the insider trades of the Individual Defendants and other insiders during the Class Period are probative of scienter.

B. Defendants Are Presumed to Know About Seres's "Core Business" – SER-109

138. Senior corporate executives are presumed to have knowledge of all material facts regarding a company's core operations. SER-109 was Seres's core business during the Class Period. It is clear that the Company's financial future depended on the results of the Phase 2 trial.

[7] *See* Damian Garde, *How biotech executives profit from legal trades*, Aug. 8, 2016, https://www.statnews.com/2016/08/08/insider-trading-biotech/.

Seres expressly stated in its March 14, 2016 Form 10-K that SER-109 is "our lead product candidate." Seres also disclosed that the very first "critical component of [the Company's] strategy include[s] . . . Rapidly advancing the development of our lead product candidate, SER-109." The Company further stated that "[s]ince our inception in October 2010, we have devoted substantially all of our resources to developing SER-109 . . ." Furthermore, Seres disclosed that in January 2016, it had secured a $1.125 billion dollar contract with Nestec Ltd. ("NHS") for the development and commercialization of certain product candidates, including SER-109. The Company's success was directly tied to the success of SER-109.

139. The most reasonable inference is that the Individual Defendants were closely monitoring the progress and results (as they came available) of the SER-109 Phase 2 trial, including any hurdles associated with CMC. In fact, this was Defendant Trucksis' primary responsibility as CMO. In this role, Defendant Trucksis would have known about the Phase 2 trial results on a rolling and continuous basis throughout the Class Period. CW1 confirms that Trucksis had direct access to the trial results as they came in, and Pomerantz's tandem stock sales suggest that he was in on that knowledge as well. Further, the FDA requires that any SAEs be immediately communicated to the sponsor (Seres), who would then have to determine the cause of such SAE and provide a report of the SAE and the probable cause to the FDA to ensure the ongoing safety of trial participants. During the Class Period, Pomerantz was a high-ranking officer – CEO/President/Chairman – who was intimately involved with, and had day-to-day responsibilities concerning, SER-109. As Seres's most senior executive, Pomerantz knew, or at a minimum, was severely reckless in not knowing, the significant hurdles facing Seres in its efforts to recreate the Phase 1 trial results.

C. The Individual Defendants Are Presumed to Know About a Core Competency of Seres – CMC

140. Seres disclosed in its 2015 Form 10-K that the management team's "core capabilities" included CMC. A reasonable inference is that Seres's top leadership would have knowledge of CMC's weaknesses as they were revealed to the Company throughout the Class Period. SER-109's success and the results of the Phase 2 trial were dependent on the strength of the Company's CMC program – a fact known to the Defendants.

141. Defendant Pomerantz was very focused on Seres's CMC capabilities and SER-109, addressing these topics often to the public during the Class Period. *See, e.g.*, ¶ 93. Similarly, Defendant Trucksis also discussed the current status of the trial in February 2016, days before entering into her 10b5-1 trading plan. *See* ¶¶ 96-98.

142. As set forth above, the Defendants made numerous specific statements regarding the Company's operations, SER-109, and Seres's purported compliance with FDA requirements. *See infra* Section V. These specific statements reflect the fact that Seres and the Individual Defendants were in receipt of information regarding each of these subjects. The only other plausible inferences that can be drawn from these specific pronouncements is that the Individual Defendants either fabricated the information that they provided to investors and the market or that they deliberately ignored information they possessed regarding such matters. In either event, such deliberate recklessness would satisfy the scienter requirement.

D. The Small Size of the Company Is Probative of Scienter

143. Throughout the class period, Seres employed less than 100 employees (according to the Company's 2015 Form 10-K, it had 86 full-time employees as of December 31, 2015). As two members of Seres's core management in such a small company, the compelling inference is that Defendants Pomerantz and Trucksis had knowledge of or recklessly disregarded the

Company's CMC failures, its difficulties reformulating SER-109 and moving manufacturing in-house, and the likelihood that the SER-109 Phase 2 trial results would not be the same as the first trial. When, as here, a company is small, it can be readily inferred that top executives are more likely to be aware of any alleged facts which strengthens the inference of scienter. Moreover, it would be implausible to suggest that senior management in such a small operation were without knowledge of matters directly affecting CMC and the potential success of its flagship product.

E. Defendants' SOX Certifications Are Probative of Scienter

144. The certification requirements set forth in SOX were designed to prevent senior executives from adopting a "head in the sand" defense to actions for securities fraud committed on their watch. The SEC has expressly warned corporate officers that "a false certification potentially could be subject to . . . both Commission and private actions for violating Section 10(b) of the Exchange Act and Exchange Act Rule 10b-5."[8]

145. As one commentator explained:

> The usual route for officers and directors facing 10b-5 liability is to plead lack of knowledge or specific intent by relying on failures in the PSLRA's proof of scienter requirement to avoid liability for having signed off on deficient reports. In an effort to counter such arguments, the SEC implemented rules pursuant to the certification provision of section 302, which specifically mandated that false certifications would expose the CEO and/or CFO to private causes of action under 10b-5.[9]

146. During the Class Period, Seres's S-1 and 2015 Form 10-K referenced herein included false and misleading SOX certifications signed by Defendant Pomerantz. In the S-1, Defendant Pomerantz represented, among other things, that:

[8] Sec. Act Release No. 8124, Pt. II. B.6, 2002 WL 31720215 (Aug. 29, 2002) (footnote call number omitted).

[9] Kourtney T. Cowart, *The Sarbanes-Oxley Act: How A Current Model in the Law of Unintended Consequences May Affect Securities Litigation*, 42 Duq. L. Rev. 293, 310-11 (2004).

> We believe that the manufacturing and formulation changes have resulted in a ***more pure form of SER-109*** that, based on pre-clinical studies, is ***comparable in potency*** to that used in the Phase 1b/2 clinical study.

147. In the 2015 Form 10-K, Defendant Pomerantz also represented that:

> The SER-109 formulation of the inner capsule has been refined to enable production to meet commercial requirements. We believe that the manufacturing and formulation changes have resulted in a ***more pure form of SER-109*** that is ***comparable in potency*** to that used in the Phase 1b/2 clinical study based on a pre-clinical mouse C. difficile model.

148. The SOX Certifications signed by Defendant Pomerantz were materially false and misleading because, at the time they were executed, Pomerantz was aware of, or recklessly disregarded, the severe deficiencies in the Company's CMC capabilities and changes made to SER-109 that likely would alter the positive outcome of the trial.

149. When reviewed collectively, as required by applicable law, Lead Plaintiffs' allegations support a strong inference of fraudulent intent on the part of the Defendants or, at the very least, the strong inference that Defendants' conduct was highly unreasonable and an extreme departure from standards of ordinary care. In either case, scienter has been adequately pled.

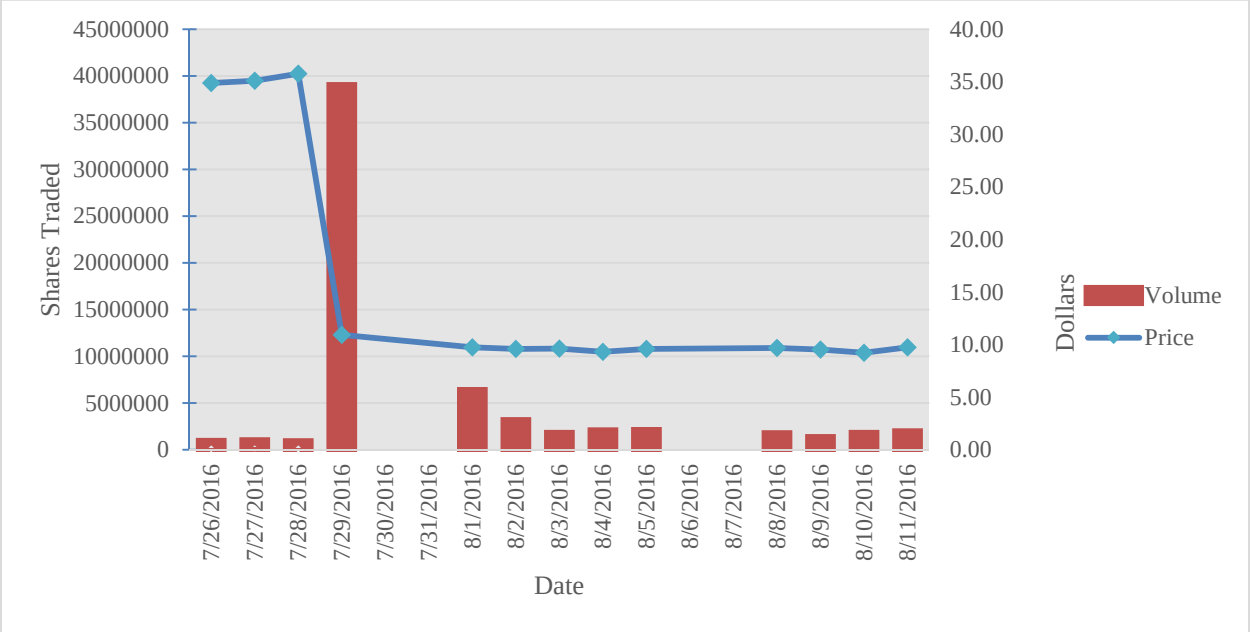
VIII. LOSS CAUSATION

150. During the Class Period, Defendants' fraudulent scheme, as alleged herein, directly and proximately caused Lead Plaintiffs and the Class to suffer substantial economic loss, i.e., damages, under the federal securities laws.

151. As set forth above in detail, Defendants presented a materially misleading picture of Seres's business practices by misrepresenting the effects of the reformulation and manufacturing changes on SER-109 during Phase 2, the Company's CMC capabilities, and the probability of success of Phase 2. Their materially false and misleading statements and omissions during the Class Period had the intended effect to cause and in fact caused Seres common stock to

trade at artificially inflated levels throughout the Class Period, reaching as high as $52.00 per share on September 9, 2015.

152. The price of Seres's common stock significantly declined when the falsity of Defendants' misstatements, the information alleged herein to have been concealed from the market, or the effects thereof, were revealed; or when the risks that had been fraudulently concealed by Defendants materialized. The following chart depicts the severity of the 72% stock drop, and concomitant spike in volume of shares traded, on July 29, 2016, when the failure of Phase 2 was disclosed.



153. This stock drop was a direct consequence of the market learning the truth and/or the materialization of the risks concealed by Defendants throughout the Class Period.

154. As a result of their purchases of Seres common stock during the Class Period at these artificially inflated prices, Lead Plaintiffs and the Class suffered substantial economic losses as the price of Seres's stock declined after Defendants' false and misleading statements were corrected and the risks concealed by them materialized.

155. On June 26, 2015, the first day that Seres shares traded, the stock opened at $28.50 and closed that day at $51.50, with over nine million shares traded. During the rest of the Class Period, on average, approximately 250,000 shares traded per day. On July 29, after the news of Phase 2 was made public, Seres stock closed at $10.94 after ***38.3 million shares*** were traded in a single day.

156. The timing and magnitude of the decline in the price of Seres common stock negates any inference that the loss suffered by Lead Plaintiffs and the Class was caused by changed market conditions, macroeconomic, or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct. Accordingly, as a result of their purchases of Seres common stock during the Class Period, Lead Plaintiffs and the Class suffered economic loss and damages under the federal securities laws.

IX. APPLICABILITY OF PRESUMPTION OF RELIANCE

157. Lead Plaintiffs and the Class are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated in part upon omissions of material fact that Defendants were under a duty to disclose.

158. In addition, Lead Plaintiffs and the Class are entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market theory, because the Company's common stock traded in an efficient market during the Class Period, as follows:

a. Seres's common stock was actively traded on the NASDAQ stock market, an informationally efficient market, throughout the Class Period. The Company's shares were highly liquid during the Class Period, with an average daily volume of 250,000 shares traded;

b. As a regulated issuer, the Company filed periodic public reports with the SEC and the NASDAQ;

c. The Company regularly communicated with public investors by means of established market communication mechanisms, including through regular dissemination of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services;

d. The market reacted promptly to public information disseminated by the Company;

e. The Company's securities were covered by numerous securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective firms. Each of these reports was publicly available and entered the public marketplace; and

f. The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock.

159. Therefore, the market for Seres common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Seres's share price. Under these circumstances, all purchasers of Seres common stock during the Class Period suffered similar injury through their purchase of Seres common stock at artificially inflated prices and a presumption of reliance applies.

X. CONTROL PERSON ALLEGATIONS

160. By virtue of the Individual Defendants' positions within the Company, they had access to undisclosed adverse information about Seres, its business, operations, operational trends, finances, and present and future business prospects. The Individual Defendants would ascertain such information through the Company's internal corporate documents, conversations, and connections with other corporate officers, bankers, traders, risk officers, marketing experts, employees, attendance at management and Board meetings, including committees thereof, and through reports and other information provided to them in connection with their roles and duties as the officers and/or directors of Seres.

161. It is appropriate to presume that the materially false, misleading, and incomplete information conveyed in the Company's public filings, press releases, and public statements, as

alleged herein, was the result of the collective actions of the Individual Defendants identified above. The Individual Defendants, by virtue of their high-level positions within Seres, directly participated in the management of the Company, were directly involved in the day-to-day operations of Seres at the highest levels, and were privy to confidential proprietary information concerning the Company, its business, operations, prospects, growth, finances, and financial condition, as alleged herein.

162. The Individual Defendants were involved in drafting, producing, reviewing, approving, and/or disseminating the materially false and misleading statements and information alleged herein, were aware of or recklessly disregarded the fact that materially false and misleading statements were being issued regarding the Company and themselves, and approved or ratified these statements, in violation of the federal securities laws.

163. As officers and controlling persons of a publicly held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, traded on the NASDAQ stock market, and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, markets, management, risk, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Seres's publicly traded securities would be based upon truthful and accurate information. The Individual Defendants' material misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

164. The Individual Defendants, by virtue of their positions of control and authority as officers and/or directors of Seres, were able to and did control the content of the various SEC

filings, press releases, and other public statements pertaining to the Company during the Class Period. The Individual Defendants were provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, the Individual Defendants are responsible for the accuracy of the public reports and releases detailed herein.

165. Each of the Individual Defendants is liable as a participant in a scheme, plan, and course of conduct that operated as a fraud and deceit on Class Period purchasers of the Company's securities.

XI. INAPPLICABILITY OF SAFE HARBOR

166. Defendants acted with scienter because at the time that they issued public documents and other statements in Seres's name they knew, or with extreme recklessness disregarded, the fact that such statements were materially false and misleading or omitted material facts. Moreover, Defendants knew such documents and statements would be issued or disseminated to the investing public, knew that persons were likely to rely upon those misrepresentations and omissions, and knowingly and recklessly participated in the issuance and dissemination of such statements and documents as primary violators of the federal securities laws.

167. As set forth in detail throughout this Complaint, Defendants, by virtue of their control over, and/or receipt, of the Company's materially misleading statements and their positions with Seres that made them privy to confidential proprietary information, used such information to artificially inflate the Company's financial results. Defendants were informed of, participated in, and knew of the improprieties and unlawful conduct alleged herein and understood their material effect on Seres's business and future prospects. With respect to non-forward-looking statements and omissions, Defendants knew and recklessly disregarded the falsity and misleading nature of that information, which they caused to be disseminated to the investing public.

168. The PSLRA's statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements pleaded in this Complaint. None of the statements pleaded herein are forward-looking statements and no such statement was identified as a forward-looking statement when made. Rather, the statements alleged herein to be materially false and misleading by affirmative misstatement and/or omissions of material fact all relate to facts and conditions existing at the time the statements were made. Moreover, cautionary statements, if any, did not identify important factors that could cause actual results to differ materially from those in any putative forward-looking statements.

169. Alternatively, to the extent that the statutory safe harbor applies to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because, at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false and/or the forward-looking statement was authorized and/or approved by an executive officer of Seres who knew that those statements were false when made. Moreover, to the extent that Defendants issued any disclosures designed to "warn" or "caution" investors of certain "risks," those disclosures were also false and misleading because they did not disclose that Defendants were actually engaging in the very actions about which they purportedly warned and/or had actual knowledge of material adverse facts undermining such disclosures.

170. Moreover, to the extent that Defendants issued disclosures designed to "warn" or "caution" investors of "risks" regarding SER-109 and Phase 2, those warnings cannot insulate Defendants from liability because Defendants, when speaking to investors, downplayed those very same risks. For example, although the Form S-1 Registration Statement states that "we have refined the formulation of the inner capsule and changed the manufacturing process that we expect

to use for commercial production"; that "[t]his formulation has not previously been clinically tested"; and that "we cannot assure you that the results of this new formulation will be consistent with those experienced in the Phase 1b/2 clinical study of SER-109," those warnings are insufficient because Defendants also stated that the SER-109 used in Phase 2 was "comparable in potency" to the SER-109 used in Phase 1b/2; that the two trials were "highly similar," and that the Company's CMC capabilities were a "core competency" that gave Phase 2 a "high probability of success." Defendants' numerous, specific false and misleading statements outnumbered and nullified the Company's generalized warnings.

XII. CLASS ACTION ALLEGATIONS

171. Lead Plaintiffs bring this action on their own behalf and as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all persons and entities who purchased the common stock of Seres from June 25, 2015, through and including July 29, 2016, and were damaged thereby. Excluded from the Class are: Defendants; members of the immediate families of the Individual Defendants; the Company's subsidiaries and affiliates; any person who is or was an officer or director of the Company or any of the Company's subsidiaries or affiliates during the Class Period; any entity in which any Defendant has a controlling interest; and the legal representatives, heirs, successors, and assigns of any such excluded person or entity.

172. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Seres had more than 39 million shares of common stock outstanding and actively trading on the NASDAQ stock market. While the exact number of Class members is unknown to Lead Plaintiffs at this time and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that the proposed Class numbers in the thousands and is geographically widely dispersed. Record owners and other members of the Class may be identified

from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

173. Lead Plaintiffs' claims are typical of the claims of the members of the Class. All members of the Class were similarly affected by Defendants' allegedly wrongful conduct in violation of the Exchange Act as complained of herein.

174. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class. Lead Plaintiffs have retained counsel competent and experienced in class and securities litigation.

175. Common questions of law and fact exist as to all members of the Class, and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include:

a. whether Defendants violated the federal securities laws by their acts and omissions as alleged herein;

b. whether Defendants' made statements to the investing public during the Class Period contained material misrepresentations or omitted to state material information;

c. whether and to what extent the market price of Seres's common stock was artificially inflated during the Class Period because of the material misstatements alleged herein;

d. whether Defendants acted with the requisite level of scienter;

e. whether the Individual Defendants were controlling persons of the Company;

f. whether reliance may be presumed; and

g. whether the members of the Class have sustained damages as a result of the conduct complained of herein and, if so, the proper measure of damages.

176. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because, among other things, joinder of all members of the Class

is impracticable. Furthermore, because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I
Violation of § 10(b) of the Exchange Act and Rule 10b-5
Promulgated Thereunder Against All Defendants

177. Lead Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein.

178. This Count is asserted pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by the SEC against all Defendants.

179. As alleged herein, throughout the Class Period, Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of national securities exchanges, made materially untrue statements of material fact and/or omitted to state material facts necessary to make their statements not misleading and carried out a plan, scheme and course of conduct, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Defendants intended to and did, as alleged herein, (i) deceive the investing public, including Lead Plaintiffs and members of the Class; (ii) artificially inflate and maintain the prices of Seres's common stock; and (iii) cause Lead Plaintiffs and members of the Class to purchase the Company's common stock at artificially inflated prices.

180. The Individual Defendants were individually and collectively responsible for making the materially false and misleading statements and omissions alleged herein and having engaged in a plan, scheme and course of conduct designed to deceive Lead Plaintiffs and members of the Class, by virtue of having made public statements and prepared, approved, signed and/or

disseminated documents that contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading.

181. As set forth above, Defendants made their materially false and misleading statements and omissions and engaged in the fraudulent activity described herein knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful deceit and fraud upon Lead Plaintiffs and the other members of the Class who purchased the Company's common stock during the Class Period.

182. In ignorance of the materially false and misleading nature of Defendants' statements and omissions, and relying directly or indirectly on those statements or upon the integrity of the market price for Seres's common stock, Lead Plaintiffs and other members of the Class purchased the Company's common stock at artificially inflated prices during the Class Period. But for the fraud, Lead Plaintiffs and members of the Class would not have purchased the Company's common stock at such artificially inflated prices. As set forth herein, when the true facts were subsequently disclosed, the price of Seres's common stock declined precipitously and Lead Plaintiffs and members of the Class were harmed and damaged as a direct and proximate result of their purchases of the Company's common stock at artificially inflated prices and the subsequent decline in the price of that stock when the truth was disclosed.

183. By virtue of the foregoing, Defendants are liable to Lead Plaintiffs and members of the Class for violations of Section 10(b) of the Exchange Act and Rule 10b-5.

COUNT II
Violation of § 20(a) of the Exchange Act
Against the Individual Defendants

184. Lead Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein.

185. This Count is asserted pursuant to Section 20(a) of the Exchange Act against each of the Individual Defendants.

186. As alleged above, the Company violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by making materially false and misleading statements and omissions in connection with the purchase and sale of Seres's common stock and by participating in a fraudulent scheme and course of business or conduct throughout the Class Period. This fraudulent conduct was undertaken with scienter and Seres is charged with the knowledge and scienter of each of the Individual Defendants who knew of or acted with deliberate reckless disregard of the falsity of the Company's statements and the fraudulent nature of its scheme during the Class Period.

187. As set forth above, the Individual Defendants were controlling persons of the Company during the Class Period, due to their senior executive positions with the Company and their direct involvement in the Company's day-to-day operations, including their power to control or influence the policies and practices giving rise to the securities violations alleged herein, and exercised the same.

188. By virtue of the foregoing, the Individual Defendants each had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content of its public statements with respect to its operations, corporate governance, and compliance with regulators.

189. The Individual Defendants acted knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful fraud and deceit upon Lead Plaintiffs and the other members of the Class who purchased the Company's common stock during the Class Period.

190. In ignorance of the materially false and misleading nature of Seres's statements and omissions, and relying directly or indirectly on those statements or upon the integrity of the market prices for the Company's common stock, Lead Plaintiffs and other members of the Class purchased the Company's common stock at an artificially inflated price during the Class Period. But for the fraud, Lead Plaintiffs and members of the Class would not have purchased the Company's common stock at artificially inflated prices. As set forth herein, when the true facts were subsequently disclosed, the price of the Company's common stock declined precipitously and Lead Plaintiffs and members of the Class were harmed and damaged as a direct and proximate result of their purchases of the Company's common stock at artificially inflated prices and the subsequent decline in the price of that stock when the truth began to be disclosed.

191. By reason of the foregoing, the Individual Defendants are liable to Lead Plaintiffs and the members of the Class as controlling persons of the Company in violation of Section 20(a) of the Exchange Act.

XIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs respectfully pray for judgment as follows:

A. Determining that this action is a proper class action maintained under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, certifying Lead Plaintiffs as class representatives, and appointing Motley Rice LLC and Cohen Milstein Sellers & Toll PLLC as class counsel pursuant to Rule 23(g);

B. Declaring and determining that Defendants violated the Exchange Act by reason of the acts and omissions alleged herein;

C. Awarding Lead Plaintiffs and the Class compensatory damages against all Defendants, jointly and severally, in an amount to be proven at trial together with prejudgment interest thereon;

D. Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

E. Granting such other and further relief as the Court deems just and proper.

XIV. JURY DEMAND

Lead Plaintiffs demand a trial by jury of all issues so triable.

DATED: February 13, 2017

Respectfully submitted,

MOTLEY RICE LLC

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CERTIFICATE OF SERVICE

I hereby certify that on February 13, 2017, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send a Notice of Electronic Filing to all counsel of record.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on February 13, 2017.

s/ Lance V. Oliver